# No. 12665

# United States
# Court of Appeals
for the Ninth Circuit.

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UNITED STATES OF AMERICA,
Appellant,

vs.

EL-O-PATHIC PHARMACY, MARTIN A. CLEMENS, HUDSON PRODUCTS COMPANY, MAYWOOD PHARMACAL COMPANY and ALLEN H. PARKINSON,
Appellees.

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# Transcript of Record
## In Two Volumes
## Volume II
## (Pages 463 to 1014)

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**Appeal from the United States District Court, Southern District of California, Central Division.**

FILED
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CLERK

Phillips & Van Orden Co., 870 Brannan Street, San Francisco, Calif.

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**Appeal from the United States District Court,
Southern District of California,
Central Division.**

Phillips & Van Orden Co., 870 Brannan Street, San Francisco, Calif.

Mr. Danielson: Dr. Heckel, please.

NORRIS J. HECKEL, M.D.

called as a witness by the government, being first duly sworn, testified as follows:

The Clerk: Your full name, Doctor?

A. Norris J. Heckel, H-e-c-k-e-l.

Direct Examination

By Mr. Danielson:

Q. What is your address, Dr. Heckel?

A. 122 South Michigan, Chicago, Illinois.

Q. What schools did you attend and what degrees did you [156] receive?

A. I received an A.B. degree from the University of Iowa and the M.D. degree from the University of Chicago.

Q. When did you receive this M.D. degree, Doctor? A. 1927.

Q. What post-graduate training have you had, if any?

A. I studied in Vienna, Hamburg and Paris in 1929 and also took some post-graduate courses in neurology at the Presbyterian Hospital in Chicago.

Q. Of what medical and scientific societies are you a member, Doctor? [157]

A. I am a Diplomat of the Society of Urology, a Fellow of the American College of Surgeons, member of the Association of Genito-Urinary Surgeons, Clinical Society of Genito-Urinary Surgeons, Western Surgical Association, American Urology

(Testimony of Norris J. Heckel, M.D.)

Association, North Central Urology Association, a member of the Society for the Study of Internal Secretions.

Q. What hospital appointments do you hold, Doctor?

A. I am Chairman of the Department of Urology at the Presbyterian Hospital in Chicago, and attending neurological surgeon at the Ravenswood Hospital, and on the advisory board of the Intensive Treatment Center in Chicago.

Q. What teaching appointments do you hold, if any, Doctor?

A. Professor of Urology at the University of Illinois College of Medicine.

Q. Are you now engaged actively in the practice of medicine, privately in practice?

A. In the practice of urology.

Q. What is urology, Doctor?

A. It is the study and treatment of the genito-urinary diseases, or diseases of the genito-urinary system in men and of the urinary organs in the females.

Q. It does not include the genital system of the female? A. That is right. [158]

Q. Have you had occasion to write or publish any articles on medical or scientific subjects?

A. Yes, I have.

Q. About how many such articles?

A. In the neighborhood of 80, I would say.

Q. Have some or any of these dealt with hormones and their effects? A. Yes, sir.

(Testimony of Norris J. Heckel, M.D.)

Q. Have any of these articles related to the effects of the male hormone, testosterone?

A. Yes, sir.

Q. And what were the sources of the information which you included in your articles, generally?

A. They were the results of investigations, from the use of testosterone upon the genital organs of man.

Q. Do you make use of testosterone, the male hormone, in your practice? A. Yes, sir.

Q. Generally speaking, under what conditions do you use testosterone in your practice?

A. In urology, we use it only for the treatment of men that have a deficiency of male sex hormone.

Q. Under what circumstances do you find that there is a deficiency of the male hormone?

A. Of the male hormone in man? [159]

Q. Yes.

A. Diseases, would you like to have?

Q. Yes, under what classes of cases is there such a deficiency?

A. Well, endocrine disturbances, which is best illustrated in eunuchism.

Q. And what is eunuchism?

A. Eunuchism is a disease characterized by a deficiency of male sex hormone, in which the body is not able to manufacture this hormone. It really is characterized by a female-male, that is, these men have the characteristics of a female; they have no beard, they have hypogonadism, hypogenitalism, a

(Testimony of Norris J. Heckel, M.D.)

high pitched voice; their extremities are out of proportion to their trunk; no beard.

Q. In your statement hypogonadism, for instance, what is the meaning of the prefix hypo?

A. Hpyo, that means below normal.

Q. And gonadism?

A. Gonad means testes. Gonad and testes are synonymous.

Q. It refers to the gland, in other words, the gonad? A. That is right.

Q. Now, are there any other types of persons who have a male hormone deficiency other than the eunuchoid?

A. Oh, yes. There are those unfortunate people that for some reason or other might have had a disease that would [160] have destroyed their testes. A young boy, for instance, that has had mumps and as a result of the mumps has developed an orchitis in which there was a destruction of part of or most of the testes.

Q. Orchitis means what, Doctor?

A. That means an inflammation of the testes. There are injuries to the testes as a result of accidents, failure of the pituitary gland, for instance, in which there is a lack of development of the testes, undescended testes, those are a few of the diseases that might be associated with a testicular deficiency, of a male sex hormone deficiency.

Q. In an instance of an actual castration, this would likewise be true, I assume?

A. Oh, yes.

(Testimony of Norris J. Heckel, M.D.)

Q. In all of those cases, Doctor, is it true that the male hormone is used, is administered to replace that which the body has failed to provide?

A. That is right.

Q. What are some generally of the symptoms of this male hormone deficiency?

A. Symptoms: Well, a patient may be impotent, for instance. It is a very common symptom. Outside of that, he has the general symptoms, he fatigues easily, he tires easily for instance.

Q. Now, Doctor, you are familiar with the symptoms in [161] which male hormone deficiency is indicated, in which male hormone therapy is indicated? A. I think I am, yes.

Q. Now, Doctor, on the basis of your education, professional training and experience, your study of the literature, your research, your conferences and discussions with other doctors, in short, on the basis of the sum of your professional knowledge, do you have an opinion as to whether the use of methyl testosterone would stimulate the growth and development of the sex organs and the male sex characteristic such as distribution of hair, muscular development and depth of voice? [162]

* * *

The Court: I think the witness may answer and should answer that question. At this stage of the evidence it is quite difficult for me to pass on whether it is material or competent in the case, and

(Testimony of Norris J. Heckel, M.D.)

subject to a later motion to strike, I will admit it and overrule the objection. [164]

* * *

A. The answer is that it would, methyl testosterone would.

Q. (By Mr. Danielson): Under what circumstances?

A. An individual that has a deficiency of testosterone or male sex hormone, as a matter of fact that is best illustrated in the eunuchoid individual in which you can make these individuals perfectly normal men by the use of this material.

Q. Now, do you have an opinion as to the incidence, the average incidence of such phenomena, of the eunuchoids, the persons to whom you have referred?

A. To the best of my knowledge, there are no available statistics. I would say that it is not too common a disease. I would classify it in comparison to other diseases as rather rare, perhaps.

Q. Could you give an opinion in round numbers as to percentage of incidence?

Mr. Elson: Isn't this immaterial, your Honor? We are concerned not with just the subject of eunuchoids. We are talking here of a male hormone deficiency and whether or not the symptoms alleged in the complaint will be relieved by an administration of it. Now, true, one of the symptoms of a male hormone deficiency may be that a person is a eunuchoid or he may be suffering from a number of conditions that the Doctor has just mentioned,

(Testimony of Norris J. Heckel, M.D.)

but, it seems to me that that is [165] immaterial to the question that is in issue here.

Mr. Danielson: Your Honor, this may be a little remote, but I believe it would be of great assistance to the court and to all parties concerned to allow the Doctor to express his opinion, if any, on the subject. The incidence of the deficiencies certainly has a bearing, it shows how few people might have this symptom. It has a bearing on the efficacy of this therapy.

The Court: That is the symptom of a deficiency?

Mr. Elson: That is correct.

The Court: The incidence of symptoms of a deficiency, yes, you may answer that.

(Pending question read.)

A. This would be purely a guess. I would say perhaps one I believe out of two or three hundred might have some evidence of endocrine disturbance.

The Court: Will you confine that now to youth? You say "boy" which indicates that you have in mind use in earlier years. I thought at the time one of the objections was made to the question was the relative number of people who might be afflicted that way. Of course, you mean males, counsel?

Mr. Danielson: Yes, males.

The Court: You mean throughout the entire population in this country, that is, the United States, or in some [166] sections of it?

Mr. Danielson: In any age group.

The Court: It is conceivable to me that it might vary between North and South, as in hot and cold

(Testimony of Norris J. Heckel, M.D.)

climates, high and low altitudes and something of that kind.

Mr. Danielson: I would say throughout the country in any age group.

The Court: Yes. Now, in any age group?

A. I would still say that the figures that I gave would be as close as I could come approximately. I don't know of anyone that has presented figures as to that. They may have. [167]

Q. (By Mr. Danielson): Doctor, are those symptoms, the symptoms indicated in that question, the symptoms of undeveloped sex organs and lack of hair and lack of muscular development and high-pitched voice, are they or could they be the symptoms of any other disease?

The Witness: I beg your pardon?

Q. (Mr. Elson, continuing): Are they the symptoms of any disease other than male hormone deficiency?

A. Those symptoms, they would be—those are really not symptoms. Those are findings that are associated with testicular deficiency.

Q. (By the Court): Arising from any source, naturally, from birth, or by accident and what not?

A. Yes, from accident, birth.

Q. (By the Court): Do you think about 2 per cent?

A. Well, I said one out of two or three hundred, I mean with some endocrine disturbance.

The Court: Oh, I got it wrong.

(Testimony of Norris J. Heckel, M.D.)

Q. (By Mr. Danielson): Now, Doctor, on the basis again of the sum of your knowledge, of your medical and scientific knowledge of hormones and their use and endocrine disturbances, do you have an opinion as to whether hormone therapy would in a man in his later 40s correct the lack of sexual power and impotence?

A. It wouldn't correct the impotence, if this impotence [168] were not due to a deficiency of male sex hormone.

Q. It would be, again, only in the event that there is a deficiency? A. That is right.

Q. Again, on the basis of the sum of your medical and scientific knowledge relative to endocrine disturbances and hormones, do you have an opinion as to whether male hormone therapy, methyl testosterone in a man in his late 40s would relieve and postpone the many conditions associated with middle age and would improve the sense of well-being?

Mr. Elson: Your Honor, I don't want to make an objection every time a question is asked, but may it be understood that there will be an objection or that there is an objection made to each one of the questions along this line involving these symptoms that I refer to in the information, in the first portion of the charge?

Mr. Danielson: That would be agreeable to the government, if it is agreeable to the court. [169]

* * *

(Testimony of Norris J. Heckel, M.D.)

The Court: I was going to suggest to Mr. Danielson that you might consider reframing the question.

Mr. Danielson: Yes, your Honor, I am perfectly agreeable to doing so.

Q. Doctor, on the basis of the sum of your knowledge, your medical and scientific knowledge relative to endocrine disturbances and the use of hormone therapy, do you have an opinion as to whether the administration of methyl testosterone would correct lack of sexual power and impotence in a person who has a male hormone deficiency?

A. It would.

Q. It would? A. That is right.

Q. Assuming the same educational background, experience and sum of your knowledge, would male hormone therapy relieve [172] and postpone the many conditions associated with middle age and improve the sense of well-being in a person who is suffering from a male hormone deficiency?

A. It would.

Q. (By the Court): Well, now, if you don't mind the interruption. But, it is my business to ascertain as near to the facts and the truth as I can. I would like to know from the witness, then, what would be the effect. Firstly, do males of that age generally lack somewhat in deficiency of this hormone?

A. It is my opinion they do not.

Q. (By the Court): They do not?

A. That is right.

(Testimony of Norris J. Heckel, M.D.)

Mr. Danielson: If your Honor please, I will lead into that.

Q. (By the Court): The next thing I want to know, then, is assuming that they have the normal amount, what, if you know, would be the effect on them as to an increased stimulation?

A. It would do two things. First, it would destroy the seminiferous tubules of the testes, and, two, it would aggravate the growth and dissemination of prostatic cancer.

The Court: Well, now, you take your witness again.

Mr. Danielson: Yes, your Honor. Thank you.

Q. Now, again assuming, Doctor, your own medical and [173] scientific knowledge and experience, do you have an opinion as to whether any man who has a male hormone deficiency, methyl testosterone therapy would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities and tendency to avoid them, nervousness, depression, general weakness and lack of physical strength?

A. It would have no effect unless those symptoms were associated with a testicular deficiency. But there are many diseases that would produce those symptoms.

Q. And again, Doctor, assuming your medical and scietific experience, education and training, your knowledge of endocrinology and male hormones, do you have an opinion as to whether with a man who has a male hormone deficiency methyl testosterone

therapy would result in improving physical and
(Testimony of Norris J. Heckel, M.D.)
mental work and would exert a tonic action resulting in renewed vigor?

A. It would, if he had a testicular deficiency.

Q. And again, assuming your medical and scientific training and knowledge, the sum of your knowledge of edocrinology in hormones, in any man who has a male hormone deficiency, would methyl testosterone therapy impart a better attitude towards social life and cause nervousness, exhaustion and melancholy to disappear?

A. It would. [174]

Q. Are these symptoms also the symptoms of any other diseases or condition? A. Oh, yes.

Mr. Elson: I object to that as immaterial.

The Witness: There is hyperthyrodism——

The Court: Just a moment, please.

Mr. Elson: Doctor, I made an objection.

The Witness: Oh, pardon me.

Mr. Elson: Object to the question on the grounds it is incompetent, irrelevant and immaterial to any issue in the case. We are talking about male hormone deficiencies. That is what the government has pleaded and it seems to me that we are getting into a field that is far removed from the subject under discussion here. That would open the door to going into that on cross-examination, your Honor, and when we wind up, it has proved nothing.

The Court: Reporter, will you read that question again.

(Question read by the reporter.)

(Testimony of Norris J. Heckel, M.D.)

The Court: That is, you mean other than a deficiency in this male hormone?

Mr. Danielson: That is correct. Are there any other pathological conditions which would have these symptoms?

The Court: Oh, well, I would say that that is a matter of common knowledge, whether they would have, but I will hear the answer. [175]

A. Many other diseases will produce those symptoms.

Q. (By Mr. Danielson): There are many other conditions? A. That is right.

Q. Now, Doctor, how is male hormone deficiency in any person determined?

A. Determined by, first, a careful history, No. 2, a careful physical examination and No. 3, there are some laboratory tests that will aid in diagnosis, such as the estimation of 17 kitosteroids in the urine.

The Court: The absence?

The Witness: The absence——

The Court: That is, in number, under 17?

A. No. That is just the name of that particular androgen is all. [176]

Q. (By Mr. Danielson): 17 is a part of that name? A. Just a name, yes.

Q. Is that a male sex hormone?

A. It is an androgen, and an androgen is another form of male sex hormone.

Q. What other methods, if any, are there for determining whether or not the male hormone deficiency exists?

(Testimony of Norris J. Heckel, M.D.)

A. The estimation of the excretion of gonadtropins also in the urine. But those laboratory procedures usually supplement or aid other physical findings.

Q. Do those examinations require special training, Doctor? A. That is right.

Q. Are there any subjective symptoms which would enable you to correctly diagnose male hormone deficiency? A. No.

Q. Would the symptoms which I have just described to you and to which you have given replies indicate necessarily male hormone deficiency?

A. You mean the nervousness and all those symptoms?

Q. That is correct. A. No.

Q. Without attempting to give a percentage, Doctor, do you have an opinion as to whether the incidence of male hormone deficiency is a common or rare phenomena? [177]

A. Rare, very rare, I would say.

The Court: Even in old men?

A. Yes, your Honor.

The Court: Impotency has nothing to do with it?

A. Nothing whatsoever; nothing whatsoever.

Mr. Danielson: Could the doctor explain that point, your Honor?

The Court: Yes. I would like to have him do so.

The Witness: I beg your pardon?

Q. (By Mr. Danielson): The fact that impotence is not a symptom of male hormone deficiency.

A. Well, impotence may be due to a variety of

(Testimony of Norris J. Heckel, M.D.)

diseases and causes, for instance, syphillis can produce it. One of the most common causes of impotence is of psycho-genic origin.

Q. And by that you mean what, Doctor?

A. Worry, fatigue, mental strain. Many people are not—a good many men I would say imagine that they are impotent. Their impotence is brought on by imagining that they are impotent.

The Court: It comes with age, at some period, does it not?

A. It is a natural process. Various stages of impotence occur with the natural process of aging, I mean the sex organs go through the same stages as other parts of the body. [178]

Q. (By the Court): Well, does sterility have anything to do with it?

A. No. Obviously, an impotent man is sterile, I mean because of his impotence he cannot discharge the spermatozoa, but a sterile man is not necessarily impotent.

Q. (By the Court): I was thinking of sterility in connection with the need for a greater supply of the hormone.

A. I did not understand your Honor.

The Court: I was thinking of sterility in connection with the need of hormones of the male type. There is no connection there?

A. No, no, no. Not unless, again, the sterility is due to an atrophy of the testes caused by a deficiency of the hormone——

The Court: Yes.

(Testimony of Norris J. Heckel, M.D.)

The Witness: ——then, that would be the result.

Q. (By Mr. Danielson): But that, again, would be one of those extremely rare conditions, is that correct, Doctor?

A. Yes, I would say it would be pretty rare.

Q. Now, Doctor, in your practice as a urologist, have you had occasion to determine, aside from these symptoms we have just mentioned, any of the results of hormone therapy? A. Yes.

Q. What are some of your observations about that?

A. You mean in treatment of prostatic cancer, for instance? [179]

Q. Yes.

A. Well, from the use of methyl testosterone we know, now, that the use of that material will aggravate prostatic cancer.

We know, now, that the use of stilbesterol, the female sex hormone, will produce a retrogression of prostatic cancer.

We know that the use of male sex hormone in any form will do wonderful things to these individuals that are suffering from a deficiency of this hormone.

Does that answer your question?

Mr. Danielson: Yes, I believe it does, Doctor.

Q. Now, Doctor, directing your attention to the use of methyl testosterone tablets containing 25 milligrams each of methyl testosterone, do you have an opinion as to whether a dosage of one tablet a day, for indefinite duration, would produce any of the effects which you have just described?

(Testimony of Norris J. Heckel, M.D.)

A. Yes, it would.

Q. What effect could that have on a prostate cancer?

A. It would cause it to grow and disseminate.

Q. In the event, Doctor, you had a patient with an early or incipient prostatic carcinoma, in your opinion would the use of methyl testosterone be indicated?

A. Oh, definitely not, contra-indicated.

The Court: Will you read the question and the answer? [180]

(Record read by reporter.)

Q. (By the Court): Would the use of the drug be indicated?

Mr. Danielson: Would it be recommended?

The Court: Oh, yes.

A. That is the same question; the same answer.

The Court: Yes.

Q. (By Mr. Danielson): Doctor, it would follow, then, that the use of the same drug, one to two tablets daily for an indefinite duration—you would have the same answer, I presume?

A. It would be worse.

Q. Are you familiar with linguets of methyl testosterone containing 5 milligrams each?

A. Yes.

Q. Do you have an opinion as to whether a dosage of two tablets three times daily of 5 milligrams each, continued for an indefinite duration, would have an effect on these conditions?

(Testimony of Norris J. Heckel, M.D.)

A. The same effect, but it would not be produced as rapidly.

Q. Do you have an opinion, Doctor, as to a dosage of tablets containing 5 milligrams—linguets containing 5 milligrams of methyl testosterone each, with a dosage of three to four linguets per day, as to whether they would have such an effect?

A. The same thing. [181]

Q. Now, Doctor, as a urologist, you have occasion to conduct examinations to detect prostatic cancers, is that not correct? A. That is right.

Q. Would you explain the effectiveness of a palpation or rectal examintion in diagnosing prostatic cancer? A. Prostatic cancer?

Q. Yes.

A. Well, in the majority of men, the diagnosis in the majority of instances is by rectal examination.

Q. Can it be detected in early stages?

A. Yes. But, in early stages, early prostatic cancer, it may be necessary to supplement the rectal examination with a biopsy. In other words, there are two other conditions that may simulate an early prostatic cancer.

Q. Will you explain that?

A. One is a stone in the prostate and the other is an area of inflammation and those are the only two things that I know of that would simulate the prostatic cancer. Most prostatic cancers, the majority of prostatic cancers arise in the posterior lobe of the prostate, which can be felt very easily on rectal examination. [182]

(Testimony of Norris J. Heckel, M.D.)

Q. Doctor, what procedure is necessary to distinguish these other two conditions from prostatic cancer?

A. Examination of the prostatic fluid for the presence of an infection, an X-ray picture of the prostate gland, of the area of the prostate gland.

Q. Do those examinations require special training, Doctor? A. Yes; I would say so.

Q. Can a diagnosis of prostatic cancer be accurately made by subjective symptoms?

A. No.

Mr. Danielson: No further questions. [183]

* * *

Cross-Examination

By Mr. Elson:

Q. Doctor, you stated this morning that the incidence of male hormone deficiency, in your opinion, was very small? A. That is right.

Q. When you had that in mind or when you made that statement, did you have in mind—I will withdraw that. Just prior to your making that statement, you were speaking of eunuchoidism?

A. That is right.

Q. And that, of course, is only one manifestation of a male hormone deficiency?

A. That is right.

Q. What are the other manifestations of it? I mean without anything that pertains to surgery or a laboratory test.

(Testimony of Norris J. Heckel, M.D.)

A. You say symptoms of male sex hormone deficiency?

Q. Not quite that. I mean the symptoms which Mr. Danielson read to you this morning, which pretty nearly cover [185] all of the field, don't they?

A. Yes; I think that is true.

Q. What I have in mind is this. I mean a man who has knowledge like a general practitioner. This man is not a specialist such as you and these other gentlemen who have testified. His knowledge lies in the field of general practice, such as lawyers experience in the field of general practice. And the man complains of several of the symptoms that were read to you this morning. In your opinion, what would that general practitioner, as a practical matter, do to assist that man in being relieved?

A. The first thing he should do is to make a careful examination of the patient to see if he can find out what is producing the symptoms. As I said this morning, there may be a number of diseases that will produce these symptoms. Do I make myself clear?

Q. Yes. I presume that one of those things, first things, that he would do would be to take a history of the patient. A. That is right.

Q. And, as a matter of fact, that is what the average doctor does to any patient that is new?

A. Yes.

Q. Then, if the history of the patient didn't disclose any condition dissociated with, putting it broadly, male hormone deficiency, what, in your opinion, would the doctor [186] do?

(Testimony of Norris J. Heckel, M.D.)

A. Examine the patient, the next procedure would be, a physical examination.

Q. A physical examination? A. Yes.

Q. That would include the usual examination that we are all familiar with, would it?

A. Yes; from head to foot.

Q. Tell me this. The average practitioner, the general practitioner, as briefly as you can, would make what sort of an examination?

A. That is a very good question and a very important question. He would go over the patient, examine his heart, lungs, reflexes and pupils and neck, chest; and then, suppose we will say for the sake of the argument that, after he had done that, he couldn't arrive or he did not have an opinion on what might be wrong with this patient; then the next thing that he would do, in all probability, would be to examine the urine to see whether there was any sugar in the urine, which would give him a clue that this patient might have diabetes, which would produce this sort of symptoms. We will assume there was no sugar, and then he would look at the urine to see whether there was albumin in the urine or casts in the urine, which would indicate that the patient, in all probability, would be suffering from Bright's Disease or some kidney disturbance. Let's assume for the sake of the argument [187] that was normal; then he would take the patient's blood pressure and see whether it was normal. Maybe the patient had a hypertension. Then, let's assume for the sake of the argument that his blood pressure

(Testimony of Norris J. Heckel, M.D.)

was normal and his urine was negative; he would probably take a blood count, as the next procedure, to see whether the patient was suffering say from anemia or had some blood disturbance.

Q. May I stop you right there? A. Yes.

Q. To be clear on it, first, all of these things cannot happen in one day, can they?

A. Oh, yes.

Q. I mean he would take a urine specimen and a blood sample and all like that but he wouldn't get the results on it until he has sent it out to a laboratory?

A. He might send it out but he could do it himself. If he would send it out, he probably wouldn't have that evidence until the next day.

Q. What I was thinking of was the ordinary general practitioner that a person goes to, whether he was equipped to conduct those tests or not himself or whether he had to send them out, and then say a day or two later the man came back.

A. Yes.

Q. You may go ahead. [188]

A. Where was I?

Q. Maybe the reporter can help you out.

A. Well, I can remember it. We got as far as the blood pressure. With the blood pressure say normal and that didn't explain the symptoms that the patient complained of, then you would get into the various should I say more complicated laboratory procedures. There might be some indication that the patient had a gastro-intestinal disturbance

(Testimony of Norris J. Heckel, M.D.)

and an X-ray picture of the stomach or an X-ray picture of the colon should be taken or a basal metabolic test made to discover whether or not he had some disturbance of his thyroid, for instance.

Does that answer your question?

Q. Yes. And I suppose there would be included in that a rectal examination?

A. Oh, yes; in the physical examination.

Q. And, if he found nothing on palpating the prostate that appeared suspicious, would it be reasonable to assume that the man was probably suffering from a male hormone deficiency?

A. No; I can't agree with that.

Q. I realize this, that you are a urologist; you are in a very specialized field. And we are talking now about the general practitioner who is not a specialist in anything. He is a master of all and so on. He is the type of doctor who is most predominant, isn't he? [189] A. That is right.

Q. We are safe in assuming, aren't we, that that type of a doctor is not going to be blessed with the specialty that you, Dr. Macdonald, Dr. Thienes and some of these other gentlemen have?

A. That is right.

Q. Now, just looking through and getting down to earth on this thing, is it a fact that such a doctor, who had gone through a complete physical examination of that patient and had been unable to find anything that looked suspicious, because of any of these symptoms, as a matter of actual practical fact

(Testimony of Norris J. Heckel, M.D.)

—wouldn't such a doctor suggest testosterone to the man to be tried for a period of say four to six weeks and see if those symptoms were relieved, as a common sense matter?

A. He might but he shouldn't.

Q. We are not talking about that. We can get into fine distinctions in medicine, and in law for that matter, as to what a man should do but they don't. We can talk in the same way about lawyers preparing cases. They should but many times they don't. Now, let's forget about what they should do and draw on your knowledge as to what the average man in general practice would do. As a matter of fact, wouldn't he do about just as I have stated?

A. I really doubt it; I really do. I doubt [190] that.

Q. Doctor, you stated something this morning that really puzzled me, among many other things, that there were very few men who went through the climacteric period. A. That is right.

Q. How can you explain, if you can, then, the vast quantity of testosterone that is sold by the Schering Corporation, the Ciba Pharmaceutical Company, and Roche-Organon?

A. Well, in answer to that question, the only thing I can say is this, that I don't know of anyone, any doctor, any scientist, any investigator, that has presented evidence by which one can make a definite diagnosis of the so-called male menopause or the male climacteric. I, myself, in my experience, have never been able to make such a diagnosis as a male climacteric.

(Testimony of Norris J. Heckel, M.D.)

Q. Right at that point, isn't it a fact that very frequently in the case of you specialists your diagnosis may not be a hundred per cent correct?

A. Absolutely.

Q. And wouldn't the margin of error increase greater, in your opinion, with the general practitioner? A. Increase greater?

Q. Yes.

A. Do you mean in making a diagnosis?

Q. In making a diagnosis, wouldn't the margin of error be greater with the general practitioner than with you gentlemen [191] who are specialists?

A. I think that is true; that is right.

Q. So, therefore, it could be very probable in the case of a general practitioner that a man might be going through the male climacteric and he wouldn't diagnose it correctly?

A. Well, what is the male climacteric? I don't know.

Q. Well, frankly, I have seen it spoken of in the literature and you probably have, too, as a condition of something or other that is comparable but not the same as the female menopause. [192]

A. As I have described the symptoms and the differences in the male climacteric?

Q. No. But it is a change of life, if you want to call it that?

A. I don't know what it is. I have never read or in talking with my colleagues learned what it was. As far as my knowledge goes, I have never been able to find an article written by anyone in which

(Testimony of Norris J. Heckel, M.D.)

they can tell how to make such a diagnosis as the male climacteric.

Q. It is referred to frequently in the articles as the male climacteric, is it not?

A. Oh, very frequently in layman's magazines and medical publications.

Q. I am going to move now over into something else before I forget it. Do you know of a doctor by the name of Deming?

A. Yes, sir; Clyde Deming of Yale University. I know him very well.

Q. Well, it is Albert Hemming.

A. I can't recall him right at the moment.

Q. To refresh your mind, I am told that he was formerly on the research staff of Ciba Pharmaceutical Corporation.

A. I can't recall him right at the moment.

Q. Incidentally, isn't it true that the body does not store hormones? [193]

A. Within a reasonable length of time, that is true. I mean most of the hormones. And I am speaking only of the male now.

Q. That is all I am talking about.

A. It is excreted in a period of 24 hours, I think, roughly, although I can't vouch for that statement.

Q. That would be sufficient, wouldn't it, for us to say with accuracy that the body does not store hormones? A. Yes.

Q. In other words, in 24 hours it is out of the body like in the food that we take?

A. Yes; I think that is true.

(Testimony of Norris J. Heckel, M.D.)

Q. You are aware, are you, that methyl testosterone may be sold, so far as any statutory requirements are concerned, without prescription?

A. I wasn't aware of it until just recently.

Q. Are you aware of the fact that at least in California it is not classed as a dangerous drug by the Department of Pharmacy?

A. I found that out this morning.

Q. I was talking about alpha estradiol this morning. A. No; I didn't know that.

Q. Coming back to the amount that is sold by these three corporations that manufacture it, Schering, and Roche-Organon and Ciba, if you can divorce from your mind your own [194] experience as a urologist, wouldn't it appear to you that, in view of the hundreds of thousands of packages that are sold in the aggregate by all three per year, that the product was indicative of considerable benefit to many, many, many men?

A. No question about that at all; wonderful. But there are many things with this hormone, that was claimed for it, that is now proven that it was of no benefit. For instance, it was supposed to have been a cure for prostatic enlargement. It was supposed at one time to have been valuable in the treatment of sterility. And those conditions now have been proven to have been false. There is no argument that this hormone produces dramatic results. There is no question about it, if it is used properly, that is, when you think that you can take a female male and make that individual into a man and establish him back

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into his community and make him a perfectly normal male, it is really amazing and astounding. [195]

Q. (By Mr. Elson): And isn't it equally astounding that a person who is suffering from a male hormone deficiency manifesting the symptoms that Mr. Danielson read to you this morning, would find that those symptoms or the majority of them would disappear?

A. Certainly, if he has a testicular deficiency.

Q. I am predicating it all on that.

The Witness: That is right.

Mr. Elson: Because that I don't question.

The Witness: Absolutely wonderful.

Mr. Elson: I don't question it. I might say that if I thought for a moment that that literature there represened that this product would be good for those conditions, even though they did not arise from a hormone deficiency, I would not be in this courtroom.

Q. In other words, the methyl testosterone, testosterone propinate has proved an immeasurable benefit?

A. There is no question about it.

Q. To thousands and thousands of men?

A. Well, I don't know—I would say that they could even go into the thousands over the world, yes, I think that would be true.

Q. We could say hundreds of thousands probably and be pretty safe?

A. I question that. That seems to be—maybe. I [196] don't know.

(Testimony of Norris J. Heckel, M.D.)

Q. Now, on this cancer business, you stated this morning, that is, I understood you to say that as a fact methyl testosterone would accelerate the growth of an incipient cancer of the prostate.

A. That is right.

Q. Do you know of any clinical evidence where that has been demonstrated as a fact?

A. Yes, sir.

Q. Where?

A. My own patients that I have observed.

Q. Was it an incipient carcinoma?

The Witness: Can I explain it?

Mr. Elson: Yes.

The Witness: Would you like to have it?

Mr. Elson: Yes.

A. A patient that was previously operated for a prostatic enlargement, prostatic hyperplasia or benign prostatic enlargement, the same thing, and for some reason or other, the histological sections revealed that this enlargement was benign or not cancerous, and rectal examination also confirmed the histological reports and studies. This patient for one reason or other was given methyl testosterone in a period of four or five weeks, five weeks I think, it doesn't make much difference, and that individual developed a prostatic cancer [197] while he was under—not developed, that is not quite the word I want to say—at least he did develop a prostatic cancer.

Q. (By Mr. Elson): Well, medically and scien-

(Testimony of Norris J. Heckel, M.D.)

tifically, does that prove that that cancer was caused by testosterone?

A. No. We don't know the cause of cancer.

Q. Medically and scientifically, does that prove that the growth of the cancer was accelerated by testosterone or something else?

A. I think it does, for the simple reason that it is not—that the growth of this cancer was so spectacular, was so rapid, that it did not follow the usual pattern of an ordinary patient that has a prostatic cancer, in other words, the individual that has prostatic cancer, we will say an incipient prostatic cancer, it may go on for four to five months before it produces any symptoms whatsoever. And here, under the stimulation, if you please, of methyl testosterone over a period of four or five weeks, the changes in this prostate and even outside of the prostate were extensive.

Q. Well, isn't that a presumption on your part, that that was the result of taking testosterone? In oher words, what I mean is this: that you have no proof that that was the cause of it, rather than something else?

A. Well, I don't think that cause—I mean that I don't think that testosterone in any form causes prostatic cancer. [198] I mean we don't know what causes it, because it has been definitely proven that testosterone in any form will activate and spread prostatic cancer.

Q. (By the Court): What do you mean by spread, Doctor? Just pardon me.

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A. Metastasize to other parts of the body. It goes into the lung and into the bones.

Q. (By Mr. Elson): Who has proven it, leaving apart your case?

A. I could give several others.

Q. Have you found any in the reported literature, any of it in the literature?

A. I think Dr. Huggins has reported that. I can't tell you right off at the moment the journal that it was published in.

Q. Recently?

A. If my memory does not fail me, I would say in the last two years.

Q. Well, then, prior to the last two years, say from 1947 and prior thereto, was there anyone who reported as a definite fact that a cancer of the prostate had been accelerated in growth by testosterone?

A. Well, of course, this whole prostatic cancer problem and its relationship to hormones is a relatively new thing. I think it was only in 1940 that Dr. Huggins came out [199] with this monumental work of his, that definitely showed and proved that you could cause a regression of prostatic cancer by the administration of estrogens, for instance. This whole thing is a relatively new thing.

Q. Well, then, prior to 1947, isn't it a fact that whether or not testosterone would accelerate the growth of a cancer in the prostate was a matter of conjecture?

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A. Well, based on clinical evidence, it was thought that——

Q. That is what I mean. A. Yes.

* * *

Q. (By Mr. Elson): Are you familiar with the work of Dr. Nathanson that I spoke of this morning?

A. No, I am not too familiar with it. I think most of his work is in the field of gynecology, isn't it? I know who he is.

Q. I think you are right. I think you are right, but in this—this was a symposium that I referred to this morning in my examination of Dr. Macdonald. It was Recent Progress in Hormone Research, Volume 1, Proceedings of the Laurentian Hormone Conference 1947. [200]

Now, Dr. Nathanson in that article, and the article is entitled "Endocrine Aspects of Human Cancer," he discusses carcinoma of the breast and so on and also cancer of the prostate gland. Now, generally speaking, and I will try to state it in substance (I think I am correct), I shall read that portion of his article. He speaks of castration or that following castration in some cases there has been evidence of the recession or inclination to dormancy of a prostatic cancer. A. That is right.

Q. And he speaks of the implication by some—that as a result of that testosterone, accelerates the growth of a prostatic cancer, because after castration of course testosterone is not produced by the testicles. A. That is right.

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Q. And so, that is the conclusion—or he does not state it as his conclusion; it is an implication or presumption. However, he poses this question and I wonder if you agree with it: that following castration there is a pathological change in the body, the pituitary gland is stimulated, action of the pituitary is stimulated, action of the adrenal glands are stimulated, and whether or not it might be because of that excess stimulation that the growth of the prostatic cancer is inhibited? Do you think there is any merit to that idea? [201]

The Witness: I am sorry. I did not quite follow that language, the last sentence of yours. Right up until the last sentence I did not quite follow that.

Q. (By Mr. Elson): Well, now, let me start over again: That after castration there is a pathological change in the body which takes place?

A. Yes.

Q. That the pituitary glands or pituitary gland and adrenals are closely connected in their activity—— A. That is right.

Q. ——with the testes. A. That is right.

Q. That, when the testes are removed, the pituitary is stimulated to secretions greater than that which they would prior to castration; the same is true of the adrenals?

The Witness: Did he say that?

Mr. Elson: That is what I understood him to say. "Orchiectomy," which is castration——

A. That is right.

Q. ——"although removing one source of andro-

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gens may permit increased pituitary activity, thus stimulating organs such as the adrenal gland to increased androgen production."

A. That is right.

Q. That is what I mean. All right. Now then, can you say as a fact, Doctor, that the increase in secretion by the [202] pituitary and the increase in production by the adrenals or some other pathological changes that has taken place in a man's body following castration is not as a fact responsible for inhibition of the growth of a prostatic cancer?

A. No. It would not inhibit the growth. It would stimulate—it might stimulate the prostatic cancer. It might stimulate it.

Q. What would?

A. I follow your thought very well. As a matter of fact, you expressed it fine. I mean, what you do when you castrate the individual, you release the governor from the pituitary and the pituitary throws out, increases its gonadtropic activity. By increasing its gonadtropic activity it stimulates the adrenal, and it is now well established that the adrenal also produces androgens, and the presence of the increased androgens in the body, as a result of the stimulation of the adrenal by the pituitary might activate or cause to grow the prostatic cancer that is there, and that is why we have, apparently why, or that is a theory at least why some of these patients are not relieved or their prostatic cancers do not regress. That is a result of the castration.

Q. But it is still a theory, isn't it?

(Testimony of Norris J. Heckel, M.D.)

A. That is right—well, they have found that the adrenals do produce androgens. That is not a theory.

Q. No. I understand that. [203]

The Witness: And it is not also a theory—this has been done on experimental animals, where they have castrated, for instance, the rat; they hook two rats together. Then they castrate one rat and that increases the gonadotropic activity of the anterior lobe of that particular rat and as a result of that, they produce changes in the other rat that is hooked up.

Q. (By Mr. Elson): I know, but right at that point, it doesn't follow necessarily that experimentation with animals is going to produce the same results as with humans? A. That is right.

Q. And it still is simply theory that castration stimulates the activity of the pituitary which in turn stimulates the production in the adrenals and so on, and that the growth of the cancer is increased?

A. I would say 95 per cent of that statement has been proven.

Q. What was the theory that you were talking about, then?

A. I don't know. What theory?

Mr. Elson: Read back to him. You mentioned something that was still theory and I just want to be certain. Can you go back there, Mr. Reporter?

Mr. Danielson: I believe he said this was the theory in the sense of rational—— [204]

(Record read by the reporter as follows: ("And the presence of the increased andro-

gens in the body as a result of the stimulation of the adrenal by the pituitary might activate or cause to grow the prostatic cancer that is there, and that is why we have, apparently why, or that is a theory at least why some of these things are not relieved, or their prostatic cancers do not regress. That is a result of the castration.")

The Witness: That last part is theory, but the rest——

Mr. Elson: Yes, that is right.

The Witness: Yes.

Mr. Elson: I think we understand each other.

Q. The fact still remains, though, doesn't it, that men are castrated, I suppose every day, for the purpose of inhibiting the growth of a prostatic cancer?

A. That is right, except there are not as many men being castrated today as there were five years ago.

Q. Well, that may be true.

A. Yes, that is true.

Q. You know more about that than I do.

A. Yes.

Q. I shouldn't say "may be."

The Witness: Yes.

Q. (By Mr. Elson): Are you familiar with this book, Endocrinology [205] of Neoplastic Diseases, a symposium? A. Yes, sir.

The Court: Well, you raise a situation there that seems queer to me.

Q. You say that castration does or at least by

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theory it did retard cancerous growth in the prostate? A. Yes, that is right.

Q. Well, it merely retards? It would not heal of its own accord, would it?

A. It is never—your Honor, although Dr. Huggins has some five-year cures, so-called five-year cures as a result from castrating men that had prostatic cancer, no one so far as I know has ever made the claim that castration or any of these various forms of therapy that are now used will definitely cure the disease. Now, they will make them clinically well so they can again resume their work.

Q. (By the Court): Well, eventually, in practically all cases, in fact it is done every day, isn't it, removal of the prostate gland will get rid of the cancer?

A. Well, that is in early prostatic cancer. That is where the cancer is confined to the gland itself. It has not been spread. When they take out the whole gland, they can get rid of the cancer.

Q. (By the Court): Well, the spread is no longer——

A. No. After it is spread, and then unfortunately [206] about 95 per cent of the men, by the time they come to their physician for their relief of the symptom, they already have a prostatic cancer that is spreading beyond the confines of the gland itself.

Q. (By the Court): Castration would not affect that in any way?

A. Yes. Now, in those instances, that is when

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the castration is indicated, after the cancer has extended beyond the limits of the gland itself and where an operation cannot be done. Now, with an early prostatic cancer, then you would not castrate the individual, if you could take all the cancer out by removing the gland.

Q. (By the Court): Supposing that it extended to the kidneys?

A. It doesn't make any difference so far as castrating an individual is concerned, kidneys, chest——

Mr. Neukom: Will you show the court one of the slides of the prostate here? This is one of the slides we showed yesterday.

The Witness: You see, when the cancer is confined right here (indicating), when it is localized, right here, when you go in and you take this whole gland out, then you get rid of the cancer, just like you take off a breast in a woman.

The Court: Yes.

The Witness: But prostatic cancers unfortunately metastasize [207] quite early, it goes to other parts of the body. Suppose it goes to the chest.

Q. (By the Court): It is more likely to do it than cancer originating in other parts?

A. Yes, than in the bladder, for instance, that is right. Then, with that individual where it has gone to other parts of the body, extended to other parts of the body, then, obviously it would not do any good to take this out, or where you have cancer in other

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parts of the body. In those two instances, there are two forms of recognized therapy, now. One is to castrate the individual or give him estrogens or female sex hormones.

Q. (By the Court): Well, castrating, would that do any more good than to stop the spreading?

A. Well, it will produce—it will cause a regression or a shrinking up of these metastatic lesions.

The Court: Well, that is all very new to me.

The Witness: Yes, it is. This thing has just developed in quite an amazing sense. For instance, I can show you X-ray pictures of a man's chest that has just been riddled by these metastatic lesions, and then put him on estrogenic therapy, this diethylstillbestrol that they are talking about here, and in six months time take an X-ray picture of his chest and you cannot see these metastatic lesions, they have shriveled up, they have disappeared—really an amazing [208] thing.

Mr. Elson: Let that go in as government's Exhibit 16, and that is the photograph or a duplicate—it is a photograph which is a duplicate of one of the pictures which was on the slide and explained yesterday by Dr. Nelson.

Mr. Danielson: Then, No. 16 is the photograph to which the witness was referring in making his last explanation.

The Clerk: That is Government's Exhibit 16 in evidence.

(The photograph referred to was marked

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Government's Exhibit No. 16 and received in evidence.)

Q. (By Mr. Elson): Doctor, you spoke about this being just recent. How recent is this?

A. Well, to be exact, I think 1940.

Q. 1940, when Dr. Huggins——

A. ——first came out with his experimental evidence.

Q. Then, when did it become the consensus of medical opinion that castration to inhibit the growth of a prostatic cancer was not so necessary as had been thought to be before?

A. Well, that still is a debatable question. The only way I could answer that is to tell you what is going on in the larger clinics.

Q. I don't think we need that. I mean as I get it, it is still a debatable question?

A. Of whether they should be castrated or have estrogens, or both. [209]

Q. Now on this incipient business, incipient means beginning, does it not? A. Early.

Q. Well, Taber's Medical Dictionary defines it as beginning. A. Yes.

Q. Would you agree with that definition?

A. Yes, I will agree with that.

Q. Now, when a cancer of the prostate is beginning, wouldn't it be almost impossible in the vast majority of cases to even know that it was there, say by—I am not talking about you as a urologist—I am talking about our general practitioner?

A. If a general practitioner is familiar with

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rectal examinations, an early prostatic cancer could or should be suspected. Now, we have to define what we mean by early incipient. Now, if it is the size of a pin head, then I question whether any one could do it.

Q. But, after all, they start from one cell, don't they? A. That is right.

Q. And they start from one cell and they grow wild and multiply, that is what generally speaking in layman's language what a cancer is, isn't it?

A. Yes, I would say that. [210]

Q. A wild uncontrolled cell?

A. Yes, that is right, exactly what it is.

Q. So, in its incipiency or beginning, or if we want to get technical about it, it is the first cell, isn't it? A. That is right.

Q. But, to be reasonable—— A. Yes.

Q. ——wouldn't it be fair to say that a prostatic cancer in its incipiency was one that was beginning and whether or not it was discoverable depended upon how far it had grown?

A. Yes, you should—you can discover it when it is about the size (I am just using some yardstick), about the size of a split pea, we will say, or something like that.

The Court: Now, pardon me. This is by-passing now. Now, what I would like to find out there: There are many tests to determine whether a cancer exists in a human body, aren't there?

A. No, your Honor. You mean laboratory tests

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or blood tests? There are no blood tests right at the moment that are——

Q. (By the Court): There are urinary tests?

A. No, no, no.

Q. (By the Court): There is a doctor here in Los Angeles, in Glendale, a Dr. Carpenter, hasn't he got a urinary test?

A. No, not to discover cancer that I know of. Now, [211] there is a Dr. Papanicalou from New York, who came out several years ago with the strain and, for instance, you would massage the prostate, we will say, massage the prostate, get the prostate fluid collected on a slide and then he would stain that slide with some special stain, and he is a very extraordinary man in cell physiology. I mean he made a special study of that, and he can tell by the examination of that slide whether there are cancer cells from the prostate. That was true. But, by that time you can also make a diagnosis by a rectal examination.

Now, Dr. Huggins. There was a good deal of publication in the newspapers just recently and he reported these investigations at Detroit about three weeks ago I think. He is working on a test that he has developed by examining the blood and this was about discovering the presence of cancer in the body, but I understand that that is not a specific test, that other diseases will also give a positive test, like tuberculosis, for instance, as I understand.

The Court: Pardon me for interrupting you there, but I rather wanted to get that in my own

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mind, as to whether there was any different methods by which cancer could be determined before it just became——

The Witness: Clinically evident?

The Court: Yes. A. No, no. [212]

Q. Doctor, we want to keep in mind this, coming back again to the charges in the information, that it may be dangerous, that is, methyl testosterone, because it may accelerate sterility and the growth of a prostatic cancer. A. That is right.

Q. And that is that would be a case where a person could, as the law permits him to do, go and buy methyl testosterone at a counter, without a prescription. That is what we have to keep in mind. We have also got to keep in mind the average circumstances as we talk about our reasonable man. And I think it is fair to say that we must keep in mind the average person who would go to the average competent general practitioner in a community and whether or not, if he went to such a doctor, before he bought any testosterone, and he had an incipient carcinoma of the prostate,—whether such a doctor, not you, would be able to find any incipient carcinoma of the prostate in that man. Now, if he did, I take it from the literature that, out of at least an abundance of caution, he would caution him against using methyl testosterone. But let's take that same individual who a few days or a week later complains of these symptoms and the doctor decides

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that he is going to try him on methyl testosterone to relieve him of those symptoms. We are talking about an incipient carcinoma That he doesn't find anything that makes him suspicious as such a doctor would go about it. There wouldn't be [213] anything so far as cancer of the prostate is concerned to prevent him from prescribing testosterone, would there?

A. If there is a definite indication for prescribing it.

Q. We are talking about an indication of how—or we will assume in our question that there was an indication to him of a male hormone deficiency and that the doctor had examined the man as such a doctor would do and had concluded that there was no suspicion of carcinoma of the prostate. I take it that such a doctor wouldn't hesitate to try the man on testosterone to see if he was relieved of his symptoms, is that right? A. Oh, I question that.

Q. Just try and divorce this business from you.

A. Yes; I know.

Q. Have you ever been in general practice?

A Yes, sir.

Q. I don't know how long ago it was but let's try and project yourself into the shoes of a general practitioner. Don't you think it is reasonable after that that the doctor is going to prescribe methyl testosterone for him?

A. I am sorry; I can't agree. I don't think the general practitioner would. Most general practitioners are very good doctors. The chances are 99

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times out of a hundred the general practitioner would find some specific reason for this [214] man's symptoms.

Q. You are putting something into my question now—— A. I am sorry.

Q. ——that isn't there.

A. All right; I am sorry

Q. Would he be safe—I will withdraw that.

Don't you think that that doctor would ordinarily, under the circumstances, try the man on methyl testosterone? A. I don't think he would.

Q. You don't think he would?

A. No; I really don't. I don't think he would.

Q. Let's assume that he did. A. All right.

Q Or let's assume before we get there that the doctor found nothing that was suspicious of cancer and so told the man. It necessarily follows, if such a warning had been on the package, it wouldn't have meant anything to the individual, would it, because the doctor had told him that he found nothing in the way of cancer of the prostate?

The Court: Due to the rather peculiar question there to the witness—isn't it true with relation to general practitioners, young and old, that they are influenced psychologically by different experiences and discoveries and what they have read and the impression that was made on them with respect to the patients? [215]

The Witness: I think that is true.

The Court: Don't some of them lean very much in favor of certain specifics and others, for some

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reason or other, form somewhat of a prejudice against them, maybe from some experience that they had?

The Witness: That might be true; yes.

The Court: At the present time, or a few years back, a very large percentage of the ordinary practicing physicians were giving lots of consideration to sulphonide drugs?

The Witness: Yes.

The Court: But it has been restricted considerably in the last few years and apparently the majority of them now go in for penicillin for just about anything?

The Witness: It all depends. They now know that these antibiotics, the sulpha drugs and penicillin, and now we have a new one, have a specificity for certain organisms, for certain bacteria, and an organism that the sulpha drugs would not influence, penicillin would. They now know a little bit more about that than several years ago.

The Court: The only reason I asked about that was on account of a question that counsel asked you, as to what the average practitioner would be likely to do with reference to this testosterone.

The Witness: Yes.

The Court: And I had a query in my mind as to what the [216] average doctor would know or think about testosterone; that some of them might be enthused about it and others might be prejudiced. Do you think so?

The Witness: That is true; that would be true, I think.

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Q. (By Mr Elson): Doctor, one of the questions that the court propounded to you made me think of something here. Coming back to our average practitioner, the average competent practitioner, general practitioner, he is a pretty busy man even today, isn't he? A. Yes; I would say so.

Q. And is it also true that with that average individual he simply does not have enough hours in the day to do his work and do all of the studying and reading of literature that he would like to do?

A. That may have been true during the war but I think now that that situation is not as prevalent.

Q. Then he couldn't take care of all his patients, that is, during the war? A. That is right.

Q. And there are many articles that have appeared, just as with we lawyers, that he ought to read probably but doesn't? A. Yes

Q. So isn't it a fact that a great deal of the working day-by-day information that that general practitioner receives [217] as to the efficacy or contra-indications and so on of a particular drug is furnished to him by the detail man from the large manufacturer suppliers, together with the literature supplied to that detail man by the manufacturer?

A. With the various county medical societies, state medical societies and post-graduate studies that they have, I would say, in answer to your question, that that is not as prevalent as one might think. It is true that large pharmaceutical concerns do send out lots of literature.

Q. And it is good information, isn't it?

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A. And a lot of it is very good information.

Q. For instance, you take outfits like Ciba, Schering and Roche-Organon, and they maintain, do they not, large and various research staffs?

A. That is right.

Q Isn't it a fact that the information that they supply in the literature to the doctors is right abreast with the times?

A. In general, yes, although——

Q. Although you disagree with some of it?

A. Some of it; that is right.

Q. However, as a practical matter, the average general practitioner is going to rely on what he reads in literature from such organizations, isn't he?

A. Not always; no. [218]

Q. In the vast majority of cases?

A. Well, of course, that is a variable thing. I don't know how you can answer that.

Q Haven't you heard this time and again, that some doctor kicks about some product and he said, "That is not what the detail man told me it would do"? A. I have heard that statement.

Mr. Elson: I don't think I have any further questions.

The Court: One will have nothing but Squibb's and another nothing but some other drug.

Mr. Elson: I have no further questions, Doctor.

Mr. Danielson: I have a few questions to clear up a few points.

(Testimony of Norris J. Heckel, M.D.)

Redirect Examination

Q. (By Mr. Danielson): Doctor, in the first place, among medical men is not cancer deemed to be early or incipient when it is small enough to be detected yet susceptible of treatment?

A. That is right.

Q Doctor, assuming a doctor who is administering testosterone to a male human patient, does he not keep that patient under regular examination or periodic examination during the treatment?

A. Yes, sir.

Q. And for what purpose is that? [219]

A. To detect any deleterious results that might occur.

Q. And if any indication of a prostatic cancer is itself determined, what does he do?

A. He stops the treatment.

Q. Doctor, do you know whether or not there is any manner in which the general practitioner does receive a constant flow of advice from the specialists and clinics?

A. Oh, yes. I should say probably two or three times every month I go to the various county medical societies and State medical societies, where we have post-graduate studies, to discuss recent advances, concerning my specialty, for instance. That is, symposiums on urological subjects.

Q. Is that a general practice throughout the profession? A. Yes.

(Testimony of Norris J. Heckel, M.D.)

Q. As to the male climacteric, Doctor, will you define what you mean by male climacteric?

A. The word "climacteric" I would say means a change, some change, that occurs from what exists previously.

Q. In a female climacteric, which I believe is an accepted phenomena, ——

A. That is right.

Q. ——what are the findings or the principal characteristics? [220]

A. Those findings in the female climacteric are very definite. The woman ceases to ovulate. In other words, the ovaries cease to make ovum And there are definite changes that occur in the ovaries.

Q. Does the production of the estrogens——

A. It changes; diminishes.

Q. Does that eventually stop?

A. I can't answer that question definitely. I am not an authority on women's troubles. I would say in some instances I think it does practically cease, and it has to be replaced by female sex hormones.

Q. If there were a male climacteric, what would be the findings of such a condition?

A. Well, if there were such a thing as a male menopause or male climacteric, there should be similar changes occur in the testes, that is, there should be a cessation of spermatogenesis. In other words, the testes would not produce spermatozoa, but spermatozoa is formed in the man, in the testes

(Testimony of Norris J. Heckel, M.D.)

of the man, as long as he lives. One of the highest spermatozoa counts I have ever observed was a billion which occurred in a man 70 years of age

Q. Would there be any comparable change in the production of the male hormone, testosterone?

A. Yes; there should. There should be a drop.

Mr. Danielson: No further questions. [221]

Recross-Examination

By Mr. Elson:

Q. There was something I wanted to ask you, Doctor, and I have forgotten it. I am not going to go into the subject of sterility except in this one particular, because I think that has been covered. You know of Dr. Hans Lisser and Dr. Robert Escamillo?

A. Yes, sir

Q. I am going to draw a shortcut. I don't think Mr. Danielson and Mr. Neukom will make me do it the hard way. In "The Urology and Cutaneous Review," Volume 46, page 87, 1944, they were reported to have said, in discussing the effect of testosterone upon the production of spermatozoa, and I am now reading, incidentally, not from the article but from a pamphlet put out by Ciba entitled "Androgenic Hypotherapy in Male Gonadism,"—the text of this says as follows, speaking of the effect of testosterone propionate and methyl testosterone on the testes: "On the other hand, there have been reported patients whose sperm counts increased after treatment to the extent that successful impregnation took place. Other authors have pointed

(Testimony of Norris J. Heckel, M.D.)

out that both number and viability of the spermatozoa can fluctuate during the continued use of androgens or that the count is 'of minor significance as compared to the enormous improvement obtained in all other respects'?"

Would you agree with that statement? [222]

A. Those patients were being treated for male sex hormone deficiency, were they?

Q. Surely.

A. Oh, certainly, I would agree.

Q. Doctor, in our discussion here I have assumed in any question in which the subject was relevant that we were speaking of a condition that resulted from a male hormone deficiency and nothing else. A. Yes.

Mr. Elson: That is all.

Mr. Danielson: That is all.

ELMER BELT, M.D.

called as a witness by the government, being first duly sworn, testified as follows:

The Clerk: Your full name?

The Witness: Elmer Belt.

Direct Examination

By Mr. Danielson:

Q. What is your address, Dr. Belt?

A. 1893 Wilshire Boulevard in Los Angeles.

Q. Of what schools are you a graduate and what years and degrees, please?

(Testimony of Elmer Belt, M.D.)

A. University of California, Bachelor's, Master's and [223] Doctor's degrees; Bachelors in 1916, Master's in 1918, and Doctor's in 1920.

Q. That is M.D., Medical Doctor?

A. Yes.

Q. And what post-graduate training have you had, Doctor?

A. I did my urologic work with Dr. Frank Hinman at the University of California and then I went to Harvard's Teaching Hospital, the Dr. Bent Brigham Hospital in Boston, to work under Harvey Cushing in brain surgery.

Q. And you are a member of what medical or scientific societies, Doctor, if you will name a few?

A. The American Medical Association, of course; the American Urologic Association; the American Association of Railroad Surgeons; the International Surgical Association, and many others.

Q. Are you a Fellow of the American College of Surgeons, Doctor? A. Yes, sir.

Q. And are you a Diplomate of the American Board of Urology? A. Yes.

Q. Doctor, have you had occasion to prepare and publish any articles, medical and scientific literature? A. Oh, yes. [224]

Q. About how many, would you estimate?

A. Thirty or forty, I suppose, but I have taken part in three books as co-author and published many articles.

Q. Have some of these articles or published books had to do with cancer of the prostate?

(Testimony of Elmer Belt, M.D.)

A. Yes. Most of them deal with the genito-urinary tract.

Q. Are you recognized in any biographical encyclopedia, such as Who's Who?

A. Oh, yes; I have appeared in Who's Who in America and Who's Who Among Physicians and Surgeons and Who's Who in Person and America's Young Men, several years ago.

Q. Dr. Belt, you are connected with the Belt Urological Group, is that correct? A. Yes.

Q. Does that group conduct any research into urological matters? A. Yes.

Q. Has that research been recognized recently?

A. Well, yes, sir; we got a blue ribbon for the best laboratory research at the last American Urologic Association meeting, which met in Los Angeles last month.

Q. Doctor, you are an urologist, is that not correct? A. Yes.

Q. How long have you been engaged in the practice of [225] this specialty? A. Since 1922.

Q. And what parts of the body are covered in the practice of urology?

A. The urinary and genital tracts, the tracts through which the urine flows and through which the seminal fluids flow.

Q. Does that include the prostate gland in a male human? A. Yes.

Q. In your practice, have you had occasion to diagnose and treat disorders of the prostate gland?

A. Yes.

(Testimony of Elmer Belt, M.D.)

Q. As such, have you had occasion to diagnose and treat carcinoma of the prostate in males?

A. Yes.

Q. Do you have any estimate as to the number of cases of that type that you have diagnosed or treated?

A. Oh, yes; I think I do. It is a little difficult to give an accurate figure of that group of cases but I imagine I have observed upward of a thousand cancers of the prostate in men.

Q. Doctor, in your practice, have you had any occasion to use or observe the use of hormones?

A. Yes. [226]

Q. Particularly the male hormone and methyl testosterone? A. Yes.

Q. Have you personally seen or treated any patients who have had adverse or injurious results from the administration of the male hormone?

A. Yes; I think I have.

Q. Could you recount to the court any specific examples of this, Doctor?

A. Yes, your Honor, I have in my care at the present time a man 48 years of age, a Doctor of Medicine, who is eminent in the field of nose and throat surgery in this area, who began taking methyl testosterone because of what he thought was sexual depletion, about eight months ago. He took material for two months. When he first noted difficulty in passing his urine, a symptom which he had not had previously, and he continued to take the material and his symptoms continued to grow worse. He

(Testimony of Elmer Belt, M.D.)

took it for a period of about four more months and then he discontinued it. But, with the discontinuance of the methyl testosterone, his symptoms of distress in urinating and difficulty of urinating did not cease, and so finally he came in to ask for an examination of his prostate, and he had a definite cancer of the prostate, which however was early enough to remove completely, and I removed it, and the section showed a very marked carcinoma of the prostate which involved about two-thirds of his prostate gland.

Q. (By Mr. Danielson): In your opinion, Doctor, did the administration of testosterone in any way influence this particular cancer of the prostate?

A. I think it very likely did, very definitely influenced it. [228]

Q. What are your reasons for your opinion there?

A. Well, in the first place, a full blown cancer of the prostate in a young man is relatively rare.

The decade in which cancer of the prostate begins to be fairly frequent is from 50 to 60. It is much more frequent in the decade of between 60 and 70, but a few cases are described as early as 45.

Q. What particular aspects of this carcinoma cause you to believe that the testosterone may have adversely affected it?

A. He did not have symptoms at all of urinary tract distress until he had taken this material for two months and then he began to have difficulty in urinating and then, subsequent urologic examination

(Testimony of Elmer Belt, M.D.)

showed that this growth was in a casing around the tube through which he had to urinate, so it was choking it down and I think it was because of the effect.

Q. Now, Doctor, do you have any opinion as to the normal incidence of carcinoma of the prostate in males, let us say, 50 years of age?

A. Recognized, the clinical carcinoma of the prostate in males 50 years of age is relatively rare. I would think that the incidence—again I find it difficult to name definite figures but what I can say is this: that patients who come to us with difficulty in urinating in the 50-year old group [229] of men, cancers of the prostate would appear probably in one out of 35 or 40 with those who came in with urinary distress, difficulty in urinating. Now, we see a very selected group of patients. They come to us because they have trouble in urinating, but those who prove to have cancer of the prostate at that young age are quite rare.

Q. What would your opinion be as to the age group of let us say 60?

A. It is more frequent. From 60 years on, about one case in 12 who come to us with urinary difficulty, the patient comes in and says, "Doctor, I am getting up at night to urinatae four or five times, I find it difficult to urinate in the daytime, it is hard to start my stream," that group of symptoms will have one in 12 who will have cancer, while 11 will have what we call benign adoma of the prostate.

Q. What do you mean by benign?

(Testimony of Elmer Belt, M.D.)

A. Benign means kindly, of course, and the growth of the prostate which is not malignant.

All cases of prostaticism producing difficulty in urination are not caused by the same thing. Roughly, there are three big cases. One is the group of inflammatory diseases of the prostate, which simply causes the prostate to shrink and therefore closes the tube for passing urine.

The other, benign adoma prostate, which are tumor growths which do not spread from the locality to other areas and therefore [230] are benign. They may produce a lot of trouble but they don't spread.

And the third, cancer of the prostate.

Q. (By Mr. Danielson): Now, does the rate of incidence of carcinoma of the prostate increase in the next decade, let us say in men of the age of 70?

A. It does, a little, it increases a little in the next decade, but from 60 to 70 on or from 60 on, the figure of one in 12 obtains pretty generally.

Q. You have testified that you have had experience with the use of the male hormone, testosterone, in various patients. In your opinion, on the basis of your education and training, experience, research and study, do you have an opinion as to whether the use of methyl testosterone would accelerate the growth of an incipient or early carcinoma of the prostate?

A. Well, I think it would, but I would like to go back to that former question, if I could, which you asked about the incidence of the cancer of the prostate.

(Testimony of Elmer Belt, M.D.)

Q. Yes.

A. And I spoke about the clinical incidence. By clinical we mean the manifestation that the patient can recognize, that shows symptoms and then the doctor will find something wrong with the instruments, the hand, his fingers or eyes. [231]

Q. That is such as the difficulty in urinating?

A. Yes, sure, where the doctor puts a finger in the rectum and finds a lump or finds residual urine and so on, something that makes the patient sick and brings him to the doctor for attention.

But, now, when you ask about the incidence of prostatic cancer in man, there is another thing that just must be said, and that is that there is a large group of cases which are not clinical, in which no symptoms have been discerned by the patient or by the doctor in examing the patient, he doesn't even uncover symptoms that the patient hasn't noticed, or signs. But that patient may have a cancer of the prostate and it may be showing no trouble and it may be dormant and riding along and perhaps it never would cause any trouble.

Q. On that same point, what is the reason for this information you are now giving us?

A. That comes out of the pathological laboratory. You know, every doctor who has his eyes on his work and really wants to learn all he can about it asks for a post-mortem examination of every patient who dies under his care. Now, he may get a lot of rebuffs, but most people are understanding and allow that kind of thing and in general that causes

(Testimony of Elmer Belt, M.D.)

the accumulation of a body of knowledge which is helpful to all of us and in this particular problem it is particularly helpful. [232]

Now, we have made observations on that point which affect us all. Dr. Moore at Johns Hopkins, his was the first series of observations, and Dr. Moore formed the habit of taking men from 40 years on and carefully slicing the prostates thin, so thin that they were almost transparent little slices and then laying them over a sheet of opalescent glass and picking out the area where the cells seemed to be growing and make a microscopic examination of those areas, and Dr. Moore was actually able to see that in one patient out of three, from 50 years on, there were little clumps of cells which were definitely cancerous in those patients, and what the future history of that patient would have been if he had lived, no one knows. But, at any rate, here were these clumps of cells that showed microscopically, and they showed there with ever increasing frequency as the age went on towards 70 and 80, and so on.

Q. What do you call these little clumps of cells?

A. Nidus nodules or beginning areas of cancer growth. Now, that is the difference between a laboratory research project and a clinical research. Now, clinically, we can take a case of an ordinary practitioner to whom a patient goes just simply because he wants a general physical examination as a routine matter. That man is obligated to put his

(Testimony of Elmer Belt, M.D.)

finger in the rectum of the male and carefully feel the prostate. [233] Now, he cannot feel all of these areas, because it would take a microscope to discern them, but he can feel them as they begin to become dangerous and become together in large enough groups to see that there is a difference in tissue, that he can feel with his fingertip, and that is when it becomes clinical.

Q. Now, you say your personal research has confirmed this same phenomena, is that correct?

A. Yes, my personal observations. It is not hardly called research. In a way it is, I guess, but for all the years I have been in practice I have always carried out autopsies wherever I could and examined the tissues myself, personally, in the company with the pathologist whose profession it is, of course. But we have confirmed that relationship that Dr. Moore has shown, by our own personal observations. Many men have it. Once, Dr. Moore showed it to us.

Q. And this has been confirmed many times since then, is that correct? A. Oh, yes.

Q. On the basis, again, of your training, education, study and research and knowledge of prostatic conditions, is it your opinion that these little nidus or little clumps of cells could, under proper environment, develop into a carcinoma of the prostate? [234]

A. Oh, yes. That is the whole significance of this work.

Q. In addition to the case that you have just

(Testimony of Elmer Belt, M.D.)

mentioned about the doctor who was presently under your care, have you seen any—are you aware of any other instances in which the administration of methyl testosterone has accelerated the growth or spread of a prostatic cancer?

A. Well, not methyl testosterone, but testosterone propionate. Actually, I guess the purpose of this inquiry—there isn't enough difference to make it worth while, but you said methyl testosterone?

Q. That is correct.

A. And I saw a case in which I am sure that the androgen which was administered, which was testosterone propionate, certainly caused a very great increase in prostatic cancer over what it would have been without it, without the administration of this material.

Now, this patient was a man of 57 who was taken sick, as far as he was concerned his first evidence of trouble was in October of 1940, and he went to his doctor in San Francisco in October of 1940, who made an examination and found a carcinoma of the prostate.

Now, the patient was run down and sick looking and felt desperate and in addition to his urinary complaints, and so, the doctor gave him testosterone propionate in the hope that [235] it would build him up and continued to give him testosterone propionate by injection in the muscles, twice a week.

And the patient came to Los Angeles in September of 1941, eleven months after this kind of treatment had been started, and he came to us, and Dr. Huggins work, which showed the very definite rela-

(Testimony of Elmer Belt, M.D.)

tionship between carcinoma of the prostate and the androgens as an increaser of cancer of the prostate, and the estrogens as a depresser of cancer of the prostate, had come out in April of 1941 and I was familiar with that work. And so I took this old gentleman off of testosterone propionate and substituted the estrogens, the female hormone, and he felt a little better, but he went on to his death and when he died—and the reason why I think that the androgen that was given to him produced a remarkable effect is because when he died, our post-mortem examination showed an extent of metastasis which is beyond anything I have ever seen, and we have shown the pictures to many physicians and no one has ever seen a case of a cancer of the prostate which was so extensive in its spread as this particular patient's, who had the androgen testosterone propionate administered to him for a year.

Q. You say you have had pictures made of that development? A. Yes, I brought them along.

Q. Would it assist you in explaining it for us by showing [236] those pictures, Doctor?

A. Yes, I think it would.

Mr. Danielson: With the permission of the court, could we have this slide shown?

Will you step down, Doctor, and there is a pointer you will be able to use.

The Witness: Well, I have several slides here which I think will clarify the subject, if the court wishes.

(Testimony of Elmer Belt, M.D.)

The Court: Go right ahead.

The Witness: The prostate is the size and shape of a chestnut in a normal fellow, and if you take a chestnut and bore a hole from the base of the chestnut through to the apex, you would have the urinary passage through which the urine flows. This spreads itself on the back of the bladder and this prostate is on the bottom of the bladder. The bladder would be here (indicating on slide).

Our urine flows from the bladder through the prostate, to emerge through this urethra, and anything that increases the bulk of the prostate takes its toll of interfering with freedom of urination, by pressing on that canal that runs through that prostate. Now, benign nidus do that and so do cancers.

The cancer nodule may be very advanced before it actually begins to exert pressure on this canal and the virtue of a rectal examination frequently in man of the cancer age, from [237] 45 on, the virtue of frequent rectal examinations is that a small nodule like that, before it is exerting any pressure on the canal and producing symptoms, can be picked up. If you find a little nodule like that, or two or three nodules or a single nodule with the general firmness of the gland, we can we can take that out surgically with a very good chance of complete recovery of the patient and a disappearance of his cancer so that he won't have any trouble again. And it was this kind of a thing that we found in our doctor that

(Testimony of Elmer Belt, M.D.)

I have told you about, and I hope that we have cured him.

But when the cancer advances into these lymph nodes around these things which are seminal vesicles or spreads into the bony structure of the patient, then we don't save him by any operation.

Now, this is the kind of a thing, the way a prostate looks after you get it all out. Here (indicating) was the uretha at the apex of the prostate. That is upside down. It is what I saw in that doctor, but it is the way it appears as you are working on the patient, and here is the seminal vesicle and here is the ampulla.

This was his little cancer nodule, and these were cancer nodules, too.

That patient made a complete recovery.

Here is the old gentleman that I spoke of—well, a 57-year old patient, he is not so old except in the fact that he [238] was so near death. His cancer of the prostate had extended in this peculiar way, and it involved all of his prostate and then it had extended in a carus or casing, clear around the rectum, which I have never seen happen in any other patient.

This is the rectal outlet here, and there it has gone clear around, the rectum making sort of a sleeve, with cancer tissue around it and then invading the urethro-perineal tissues, that is to say, behind the whole back of the man, behind the peritoneum up into his liver and surrounding his intestines, and that is the liver we see there through

(Testimony of Elmer Belt, M.D.)

the opening on the bottom and will turn that liver up out of there, and you see these tremendous masses of cancerous tissue throughout that specimen.

And lifting the liver out and putting it in a big basin, the size of the liver is seen to be five times the normal liver size.

And when you cut that liver in two, you can see that it is just completely replaced by these great cancer nodules.

Now, it is not infrequent for cancer to extend into the liver, but to occur completely in that way and to throw so many metastasis throughout this elderly man's body is the unusual thing.

You see, that is almost a complete replacement of that vital organ with cancerous growth, and the very magnitude of [239] the growth is the thing that makes me feel that the androgen administered to him was in such magnitude, because of the two things taken together, a case in which testosterone was administered for a course of a year, which also showed more metastasis than anyone in this area had ever seen from this disease—now, this little chart. In a way, I really ought to leave this for Charlie Huggins, but perhaps I can clarify what he is going to say to you, by telling you of his work. He might be too modest.

Dr. Huggins has taken two immature prostates in dogs and has given them injections of testosterone propionate. These were little puppies, and the zigzag rising curve here shows that in a period of six days, on 10 milligrams of testosterone propionate

(Testimony of Elmer Belt, M.D.)
daily, these prostates came to rapid maturity, the puppies had adult prostates at the end of that six-day period.

Now, the opposite effect is shown here on the volume of the seminal fluid, in the giving of the female hormone estradiol benzoate.

Here is a fullblown male dog, with lots of sexual pep and vigor, and the dose of female hormones begun to shut off that progress of seminal fluid, drops down nearly to zero and since then, when the female hormone is stopped, bang, up goes the activity of the prostate and seminal vesicles again, showing the tremendous depressing effect of the female [240] hormone on the dogs' prostate, seminal fluid and prostate.

And this is the same sort of a grouping in another case. Dr. Huggins has done that again and again. This was a very interesting corrolary of that same thing.

Here is a bilateral orchectomy. He took off both testicles from this dog, and the dog immediately drops in all activity, of both prostate and seminal vesicles, they just shriveled up and quit.

Then he began injections of 25 milligrams a day of testosterone propionate and immediately the dog's prostate makes a recovery back toward normal. And the minute he stops giving that material in the ordinary sized dog, the prostate shrivels up again and goes back to nothing.

Now, here is a very interesting experiment which combines two things. The dog is castrated and he

(Testimony of Elmer Belt, M.D.)

drops to nothing so far as his prostate secretion is concerned. He is given testosterone propionate in 10 milligrams daily amounts and he starts on his upward climb toward normal.

Then, in addition to this testosterone propionate, he is given stillbestrol in a very small amount, 2/100 of a milligram, and it doesn't do anything for that that can be seen on the chart.

Then he gives a tenth of a milligram and he gets a pause. Then he gives 2/10 of a milligram and the rise levels off. [241]

So, 2/10 of a milligram of stillbestrol daily just about neutralizes 10 milligrams of testosterone propionate daily. The two things are chemical antitodes.

Then he gives 4/10 of a milligram and the curve begins to go downward, the curve of testicular activity of the prostatic activity and then he gives 6/10, and the curve of prostate activity goes clear down to zero again.

The point of it is that 6/10 of a milligram of stillbestrol a day counteracts completely 6/10 milligrams of testosterone propionate, and the experiment shows that the two are physiological opposites.

About the time that Dr. Huggins had made these observations work came out to show that acid phosphatase, one of the enzymes in the human body, that the body became flooded with this acid phosphase in cancer of the prostate, in advanced cases of cancer of the prostate the patients had a large amount of this acid phosphatase. Dr. Huggins

(Testimony of Elmer Belt, M.D.)
knew that acid phosphatase was made in the prostate, and he felt, then, that this would be a good criterion to show if stillbestrol would cause a deleterious action on cancer of the prostate, make the patient better.

So, he examined some of the nodules of metastaic cancer in distant places, and found that they were parts of these acetate phosphates.

Now, when he gave stillbestrol as a result of this observation [242] to cancer of the prostate patients, the acetate phosphatase dropped away down here to zero and with a corresponding increase in well being on the part of the patient and correspondingly, when he took off both testicles and prevented the patient from being flooded with his own testosterone, the acid phosphatase again dropped to normal.

Now, these patients improved in direct correspondence to the dosage of stillbestrol that they were getting.

This complicated looking curve simply shows case observations and shows that in a grouping, it happened to be 85 patients in this total group with cancer of the prostate, when treated with still bestrol, they all suffered a gain in weight, they all suffered a rise in their red cell count and haemoglobin and all underwent a correspondingly great increase in well being.

Now, this work of Dr. Huggins has shown us definitely that testosterone propionate, that is the

(Testimony of Elmer Belt, M. D.)

male hormone which the male makes in the natural course of his ordinary existence, is a stimulating factor for carcinoma of the prostate and helps carcinoma to become widespread and probably to form and to keep going, and that, on the other hand, if this testosterone propionate is stopped either by neutralizing it with stillbestrol or by removing the source, by taking off the testicles, that for a time the patient goes into a sort of well being which was unprecendented in our knowledge [243] of cancer prior to this work. We had never seen anything like this.

Of course, unfortunately the body, like it does to all things, adjusts itself to these differences and in time the patient is again swamped with this cancer and goes to his death.

Although there are on record cases which have gone along since 1940, now, without any evidence of cancer, after the cancer has once been overcome by stillbestrol or by abolition of the testicles or by both, taken together. There was an ever-increasing number of such cases which have been apparently cured, although no doctor speaks of cancer as being cured. We know too well that even after 25 years, a cancer which has apparently been cured and forgotten, suddenly blossoms out and overwhelms the patient.

There are many more things about this that are unknown, than are known.

Q. (By Mr. Danielson): Now, Doctor, in the case of these small clumps of cells that you men-

(Testimony of Elmer Belt, M. D.)

tioned that are determined by pathological examination of the prostate or by laboratory examination of the prostate, you say on the basis of your opinion, would testosterone administered to such a person affect the growth or development of these clumps of cells?

A. I believe that it would hurry it, yes, [244] probably light it up and cause it to become active instead of dormant.

Q. Now, specifically, do you have an opinion as to whether testosterone in the form of 25 milligram tablets, methyl testosterone administered one tablet daily for an indefinite period of time—could that have such an effect, in your opinion?

A. I think it well could.

Q. Would 10 milligram tablets of methyl testosterone, again administered one daily for an indefinite time, or three daily for 10 days, followed by one daily for an indefinite time, have such an effect, in your opinion?

A. Yes, I think this substance is dangerous in that respect, that it could aggravate a carcinoma of the prostate or bring it from a dormant state into active state and destroy the patient.

Q. Are you familiar with methyl testosterone in the form of linguets, Doctor?

A. Yes, indeed.

Q. In your opinion, could linguets containing five milligrams of methyl testosterone, each, administered at the rate of three to four linguets per day, for an indefinite time, have such an effect?

(Testimony of Elmer Belt, M. D.)

A. Yes.

Q. Doctor, in your opinion, is there any difference in the therapeutic effect of testosterone in its different forms? [245] By that I mean methyl testosterone, testosterone propionate and so forth?

A. Yes, there is a little difference in their therapeutic forms, in their action.

Q. Could you elaborate on that, please?

A. Oh, it is pretty difficult to say definitely what the difference is. Testosterone propionate tends to be held by the tissues a little better than methyl testosterone, a larger proportion of the methyl testosterone appears in the urine and is thrown out, but I think that the body metabolizes both of these substances into the same thing, in its use, with time, and that one is a little bit more wasteful than the other, and that is the only difference.

Q. Well, as the body uses these two drugs, however, is the use the same?

A. Yes, the body converts them into the same thing.

Q. Now, Doctor, you have mentioned that you have used methyl testosterone or testosterone in some of your treatment. Are there any instances that you know in which methyl testosterone or testosterone can have a good effect?

A. There are many instances in which it is a drug which is very valuable.

Q. What precautions, if any, are necessary prior to such use?

(Testimony of Elmer Belt, M. D.)

A. We have several tests for the presence of cancer and [246] they should be applied, cancer of the prostate I am speaking of now. One is the digital examination that I have tried to make clear.

Another is the level of acid phosphatases in the bloodstream which I mentioned. And then there are two other tests which are very recent, one a test of the proteins of the blood which shows the presence of the cancer or the absence of it, which is useable before any other clinical test can show the presence of cancer, that should be applied. And still another test, which is also a protein, a blood protein test.

Q. You feel that such precautions are a prerequisite to any testosterone therapy then, is that correct?

A. That is right, except in groups where cancer of the prostate is not liable to occur and by that I mean the cases in which testosterone is particularly valuable, or the groups of young individuals who show a definite endocrine deficiency in regard to testosterone and who need the substance in the normal process of their growth and development.

Q. How is it possible to determine whether or not there is such an endocrine deficiency?

A. There is a clinical method, observation of the patient. You would recognize an endocrine deficient person if he sat here, possibly, if you were familiar with it, through his changes in his growth and certain texture of the [247] skin and so on. That would be the clinical type of thing.

(Testimony of Elmer Belt, M. D.)

Then, there is the laboratory work. We have what we call the 17 ketosteroids, which appear in the urine in certain quantities and the amount there can be measured, and if they are measurably low, it means that a deficiency exists in the hormone-producing structures of the body.

Q. It is easily or relatively easily recognized in groups such as the first—I am referring now to the eunuchs and eunuchoid groups?

A. That is right. During the war, the last war, we had a large group of fellows who lost their testicles from land mines. On land mines they stubbed their toe against them and the thing explodes, and on the upward explosion it carries off their testicles because they are projecting just a few millimeters beyond the level of the thighs, and they are ripped off, and those boys have to have this help, and testosterone linguets, testosterone propionate, of course, are just invaluable remedies. They bring this lad, who had been pale and lethargic and disinterested and useless into active life so that he cannot be discerned from anyone else.

Q. In a person who is apparently normal physically, who has all of the apparent physical parts of his body, what examination would be necessary to determine whether there is such an endocrine deficiency? [248]

A. Well, the 17 ketosteroids might show it, the application of that test. The principle of that is everyone produces more and much more testosterone propionate than he needs, at any given age

(Testimony of Elmer Belt, M. D.)

of his life. The testicles overwork. So do the ovaries, for that matter. And an amount of this material, testosterone propionate, on the one hand, and estrogenic substances on the other in the female, is thrown out in the urine constantly and that is measurable, it is recoverable, and you can see the extent to which that loss of substance occurs and in that way you can measure whether or not the testicles are producing the normally expected overflow of this material.

Q. Now, those examinations you have just mentioned, do they require special training, Doctor?

A. Oh, yes, they do.

Q. Are there any subjective symptoms of this male hormone deficiency which a layman could recognize and accurately use to diagnose such a condition?

A. Oh, gosh, I wouldn't think a layman could know. He might confuse almost anything with loss of what he thought was his normal quantity of hormones. If he just began to feel tired and run down or if his tennis arm was not satisfactory, or if he made too many strokes in his game of golf, he might decide that he was passing into the climacteric and therefore should take a few testosterone linguets. [249]

Q. Doctor, in your experience, has such been the case?

A. Oh, yes. We are taking people off of this stuff all the time.

(Testimony of Elmer Belt, M. D.)

Q. And what, as the result of your studies, has caused them to start using this preparation?

A. They read in the newspapers they must. We have a gullible American public.

Mr. Danielson: No further questions. You may cross examine.

* * *

The Court: I want to get one thing clear. I have got to analyze this thing the best that I can as we go along. I don't know what the cross-examination may develop. But at this stage I would like to know this, as your opinion, you understand. Supposing after a careful examination of a subject, no nodules or other indications or other incipient cancer are found. Do you think it would still be dangerous or conducive to the development of cancer in the prostate to take this hormone, testosterone? [251]

The Witness: Yes; actually, it would.

The Court: Then, tell me for what reason and upon what you base your opinion.

The Witness: Because you can't feel all the areas that might be involved.

The Court: You mentioned some other test in addition to the digital test.

The Witness: Yes. If the protein test was made, it would be less likely to cause trouble, but even this giving should be all controlled by relative frequent examinations. I think, if testosterone propionate is used in an individual in the cancer group, he should have the benefit of these tests

(Testimony of Elmer Belt, M. D.)

which are necessary to show the presence of early cancer, frequently, at least twice a month, as a control.

The Court: In your judgment, what would be the effect on the patient by reason of the administration of this hormone, in the dosages that have been mentioned here, 25 milligrams daily, and then perhaps tapering it off after the first week and so on, and running for a period of two or three months? What, in your opinion, would be the effect on the patient? Would it have a deleterious effect and, if so, why?

The Witness: It could be a deleterious effect through stimulating a cancer which was latent or dormant.

The Court: Supposing no cancer came into the picture.

The Witness: It need not necessarily be deleterious then. [252]

The Court: Would it be beneficial or stimulating or rejuvenating or invigorating?

The Witness: There are a few special cases in which testosterone propionate is stimulating and of value over short periods of time, and that applies to methyl testosterone taken by mouth, too. What I am pleading for in this case is that it be adequately controlled, with careful observations, in order not to run the patient into danger, because the good advantage this material does is out of all proportion in relation to its harm. The amount of

(Testimony of Elmer Belt, M. D.)
potential harm it has is much more than the good it can do if used unbridled. [253]

* * *

CHARLES HUGGINS, M.D.

called as a witness by the government, being first duly sworn, testified as follows:

Direct Examination

By Mr. Danielson:

The Clerk: Your full name?

A. Charles Huggins.

Q. (By Mr. Danielson): What is your address and present occupation, Doctor?

A. My address is University of Chicago, Chicago, Illinois, and my present occupation is Professor of Urology at the University of Chicago.

Q. Of what schools are you a graduate, giving the years and degrees, please?

A. I am a graduate of Acadia University in Canada, Bachelor of Arts, 1920, a graduate of Harvard Medical School of 1924, Doctor of Medicine; I have honorary degree of Doctor of Science, of Acadia University, 1956; I have an honorary degree, a Master of Science from Yale University, 1947.

Q. What post-graduate training have you had, Doctor?

A. Well, I have had three years of training in surgery at the University of Michigan, 1924 to 1927.

(Testimony of Charles Huggins, M.D.)

Q. Are you a member of any medical or scientific societies?

A. I am a member of the National Academy of Science, member of a number of professional societies, for example the American Urology Association, the American Association of Genito-Urinary Surgeons; American Medical Association.

Q. Yes. Those are representative societies, is that correct? There are others?

A. Well, let us put in the American Association for Cancer Research.

Q. Do you now or have you had any hospital appointments, Doctor?

A. I am the head of the urology department at the hospital of the University of Chicago and have been so for 20 years.

Q. And you do hold a teaching appointment at the present, at the University of Chicago?

A. That is correct.

Q. Have you held any other teaching appointments?

A. I have been instructor in surgery at the university of Michigan.

Q. Have you ever practiced medicine, [257] Doctor?

A. I practiced medicine since 1924.

Q. And what is your specialty, if any?

A. I profess to practice and teach urology.

Q. Have you written or published any articles on medical or scientific subjects?

(Testimony of Charles Huggins, M.D.)

A. I have published approximately 150 papers on urological and scientific subjects.

Q. Has any of them related to the use or function of the male hormone?

A. Since 1938, our work has been almost exclusively related to the male hormone and its action in normal and cancerous individuals.

Q. Has some of these papers from this research related to the function or effect of the male hormone upon prostatic cancers?

A. We have published about 20 papers in this field.

Q. Doctor, have you had any personal recognition for your work in this field?

A. I have had the honor of being awarded several prizes by national scientific bodies, for this work.

Q. Would you name a few of these, please?

A. Well, in 1942, I was awarded the Judd prize by the Memorial Hospital for treatment of cancer in New York City. This was a prize of $1,000.

Q. Have there been some other such recognitions, [258] Doctor?

A. In 1943 I received a Mayer award of the National Academy of Sciences, for what they considered the most significant work in cancer in the previous five years.

Q. Have there been any others?

A. In 1948 I received an award of $1,000 from the American Urological Association for what they called outstanding research in the function of the

(Testimony of Charles Huggins, M.D.)

male genital tract; and in 1948 I received a septenial prize of $3,500 from the American Academy for Arts and Sciences in Boston, Massachusetts, given for what they call outstanding contributions to the treatment of men with difficulties in the genito-urinary field.

Q. Have there been any other such recognitions or prizes or awards, Doctor?

A. I think this is perhaps enough, sir.

Q. Thank you very much.

You are familiar, are you, Doctor, with the effects of the male hormone on the human body?

A. Yes.

Q. Are you familiar with the effect of the male hormone testosterone on males in their late forties or in their middle age?

A. We have studied males of many ages, young and old, both human and animal, and I think I have a reasonable familiarity [259] with men in their late forties as well.

Q. Are you familiar with the effects, then, of the male hormone on male humans with a male hormone deficiency?

A. We have not seen many patients with a male hormone deficiency. I think that it is a very rare condition, but we have treated possibly 30 patients in the last 11 years with male hormone deficiency.

Q. Under what conditions does a male hormone deficiency occur in a male human?

A. We think in human beings, male hormone deficiency occurs more commonly in two states, one

(Testimony of Charles Huggins, M.D.)

which we in medicine call hypogonadism, where the male sex hormone is produced in small amounts or is not produced at all, a congenital state; second is the castrate male, where the testes have been removed as a result of operation or accident. These are the chief types of male hormone inadequacy.

Of course, in very grave states of illness, such as an advanced tuberculosis, there is a hormone deficiency not related to congenital causes or to accidental or purposeful removal of the testes.

Q. Could you give us an opinion as to the incidence of this latter situation in the advanced case of tuberculosis?

A. I think that in very gravely ill patients, bedridden patients with advanced disease, it is rather common. But I do not think that it occurs in quasi-normal individuals, [260] people who are able to be up and around, for example.

Q. Do you have an opinion as to the incidents of hypogonadism in human males, Doctor?

A. In a hospital population, we see those about twice in a thousand admissions to the hospitals, so that it is an extremely rare condition.

Q. That would be two out of a thousand admitted to the hospital?

A. Yes, as a maximum, two. Perhaps one per thousand, between one and two per thousand patients coming to the hospital with disease have hypogonadism.

Q. And, Doctor, what do you mean, precisely, by hypogonadism?

(Testimony of Charles Huggins, M.D.)

A. Hypogonadism is usually—it is not always—a congenital state wherein bodily growth is reasonably satisfactory but in which the external genital organs remain undeveloped, the secondary sex characteristics remain undeveloped; the male will speak with a soprano voice, he will have no growth of hair on the face, on the chest or in the genital region. There is, in these patients, failure, complete failure of the erections of the penis, a complete failure of ability to have sexual relationships. This is hypogonadism.

Q. As to the definition of the word, then, hypo I understand means below or under, or below normal, is that correct? A. That is correct. [261]

Q. And the word gonad refers to the——

A. Testes.

Q. I see. Now, is this situation a transient condition or is it a condition that is with a person permanently?

A. This is a condition that is permanent, except that it can be adequately treated by certain hormones.

Q. Now, Doctor, do you have an opinion as to the incidence of castration in human males?

A. Castration in patients, as they present themselves to a clinic, is quite rare, except in patients who have had castration to eliminate the male sex hormone, which is a factor in cancerous prostate.

Q. Do you have an opinion as to whether the incidence of castration is as great as that of hypognadism?

(Testimony of Charles Huggins, M.D.)

A. Until 1941 we practically never saw a castrate in the clinic.

Since 1941, since our work on the damaging effect of the male sex hormones on certain cancers of men, since this has been widely adopted, we see now considerably more patients with castration than we saw before.

Q. And in referring to these persons among persons admitted to the hospital, these are persons who are already ill for some reason or other, is that not correct? A. That is true.

Q. Coming for treatment. Now, Doctor, you have mentioned [262] that in connection with hypogonadism there can be effective treatment with hormones. Would you explain that, please?

A. Well, by giving androgens, the male sex hormone, one can restore the sexual drive of these people, one can restore the secondary sex characteristics. Of course, one cannot restore the testes as such. And that is the standard treatment.

Q. Doctor, do you have an opinion as to what would be the daily requirement of androgen, the male hormone, to produce this effect on a hypogonad?

A. We treat patients with one of two types of hormones, either injections of testosterone propionate, and there the daily dosage is about 5 to 10 milligrams; and another way of treating these patients is by methyl testosterone, by mouth, and there the daily dose is 10 milligrams by mouth.

Q. Is the 10 milligram dosage of methyl testos-

(Testimony of Charles Huggins, M.D.)

terone adequate to convert the hypogonad into an apparently normal male?

A. That is correct. 10 milligrams will restore, from the standpoint of secondary sex characteristics, a hypogonad patient, to normal.

Q. And will enable him to maintain that status?

A. They will maintain it as long as the methyl testosterone is administered. [263]

Q. What dosage would be required for the same purposes, in the case of a castrate, Doctor?

A. The same dosages.

Q. 10 milligrams daily of methyl testosterone would be effective?

A. We think the 10 milligrams of daily administration by mouth of methyl testosterone is equivalent to what a normal healthy young male is producing in his own gonads.

Q. Could you give us a comparative effect, a comparative potency of injected testosterone propionate and orally administered methyl testosterone?

A. Injected testosterone propionate is roughly twice as strong as methyl testosterone taken by mouth. [264]

Q. Doctor, you have mentioned that these dosages of 10 milligrams daily of methyl testosterone are adequate to produce these wonderful and beneficial effects on hypogonads and castrates. Do these drugs produce any toxic effects on the human male?

A. We must divide the human male into well patients and ill patients. These androgens are very powerful agents. One cannot take, in my opinion,

(Testimony of Charles Huggins, M.D.)

androgen in the same way that one can take a drink of water or a piece of candy. You must take them with impunity. These things, when they are given, definitely cause derangement of the organism. For example, a person taking methyl testosterone or testosterone propionate thereby inhibits his normal mechanism for producing the male sex hormones.

Q. What would be the effect of that?

A. Well, this is rather complex physiology. There is a system called the male genital system consisting of the pituitary and the testes and the secondary sex characteristics. If one takes, administers or has administered to him, one of these agents, that deranges the factory mechanism. If one takes methyl testosterone or any other testosterone, that will make the pituitary gland function at a low level so that, when a persons stops such administration of the drug, then the pituitary functions at a low level for a number of months.

Q. Is that harmful or beneficial?

A. That is harmful. A second harmful effect of a [265] normal person taking testosterone is that it cleans out the testes of the germ cells, the spermatozoa, so that a patient, therefore, is unable to fertilize a female.

Q. That is, it cuts down on the production of sperm, is that right?

A. It cuts down very marketedly on the production of sperm. These are the effects in a normal person. In an ill person other undesirable effects are manifested.

(Testimony of Charles Huggins, M.D.)

Q. Generally, without great detail, what would be the nature of such effects?

A. The clearest cut instance is activation of cancer of the prostatic gland.

Q. Doctor, by androgen you refer to methyl testosterone and testosterone propionate, is that correct?

A. Substantially correct. There are other androgens. Androgen and the male sex hormone and testosterone may be considered, roughly, parallel, synonymous.

Q. Is androgen a generic term which includes these others?

A. It includes all drugs or chemicals which can cause secondary sex characteristics in males.

Q. Doctor, you have mentioned about these dosages which have the beneficial and toxic effects on abnormal and normal humans. Can you tell me whether you have an opinion, based on your education, training, experience, study and [266] research, as to whether tablets containing 25 milligrams each of methyl testosterone, taken one each day for a definite period, would have these effects on a male human?

A. 25 milligrams a day would certainly have these effects.

Q. Either the good or the bad, is that correct?

A. That is right.

Q. On the same basis, Doctor, of your training, and the sum total of your knowledge, do you have an opinion as to whether 10-milligram tablets of

(Testimony of Charles Huggins, M.D.)

methyl testosterone, taken one each day for a definite period, would have these effects?

A. It would have the same beneficial and, also, harmful effects.

Q. And, by the same token, a larger dosage of the same would have more pronounced effects?

A. That is correct.

Q. Do you have an opinion, on the basis of the sum of your knowledge of this subject, as to whether 5-milligram linguets of methyl testosterone, taken at the rate of two linguets three times daily, would produce such effects?

A. My opinion is that they would produce such effects.

Q. Both the good and the bad, is that correct?

A. That is correct.

Q. Doctor, you have mentioned that you are familiar with the use of testosterone in the treatment of hypogonads [267] and castrates, as well as normal people. In instances of male hormone deficiency, are you familiar with the sypmtoms of such a person? A. That is right; I am.

Q. On the basis of your training, education, experience, study, research and the sum of your knowledge, do you have an opinion as to whether the use of methyl testosterone would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of the hair, muscular development and depth of voice?

A. I do.

Q. What is that opinion?

(Testimony of Charles Huggins, M.D.)

A. The opinion is slightly complex since it has different effects, quantitatively speaking, in hypogonad people as opposed to the effects in a normal healthy male. In a child, tremendous growth of the penis, and secondly, sex characteristics, change in the depth of the voice, growth of the hair on the face and on the chest, occur. In hypogonadism and in children these effects are very marked, indeed. These effects are, quantitaitvely, very much less in a normal healthy male.

Q. In a castrate is there any less effect, or any such effect?

A. In a castrate it depends whether the castrate was—whether the procedure of castration was done at an early [268] stage, before puberty or after puberty. In general, androgen stimulates a castrate very much as it does a child or a patient with hypogondalism. If castration has been done late in life, say, for example, at the age of 30 or 40, it has less effect in restoring hair and depth of voice than in a young person.

Q. Do you have any opinion, Doctor, as to how early an age a child would be so affected by androgen therapy?

A. From the age of one year on there would be tremendous growth; perhaps before one year. I don't think anyone has given androgen to a child of less than one year.

Q. And a small boy would be so affected, is that right?

A. To give androgen to a child of five, ten or

(Testimony of Charles Huggins, M.D.)

twelve, will make a tremendous sex drive, growth of the penis and desire to have sexual relationships.

Q. Could it render him sexually mature at such an age?

A. It will render him sexually mature at such an age with the exception that sperms are not produced. They will render a child sexually mature at the age of two years.

Q. Doctor, again on the basis of the sum total of your knowledge of this subject, do you have an opinion as to whether androgen therapy, the use of methyl testosterone, would correct the lack of sexual power in impotents?

A. Impotence is a rather complex situation, too. It occurs for two reasons. In general, we classify impotents [269] as psychogenic, which accounts for 95 per cent of the patients we see with impotence in normal healthy people, and the second classification is a deficiency of male sex hormones. The castrates, as a result, are impotent. The hypogonad patients are by function impotent. The effect of testosterone on impotence depends on the classification of the disease. If it is due to a hormonal deficiency, then testosterone will restore impotence to potency. On the other hand, unfortunately, 95 per cent of the patients that we see, or perhaps fortunately, in the clinic have psychogenic impotence.

Q. Just what do you mean by psychogenesis?

A. That is medical jargon. Psychogenic impotence is impotence where there is no deficiency of male sex hormone production, where it is believed,

(Testimony of Charles Huggins, M.D.)

for functional reasons, such as overwork, psychiatric conditions, neurathenia and things like that, a person is unable to have intercourse with a female. In this type of impotence the administration of androgen has no effect, and this was discovered in our clinic, so we know about these things.

Q. You say this was discovered in your clinic?

A. That is right, that androgen had no effect.

Q. Was some research conducted which produced this information there?

A. Yes; we studied a large series of patients with impotence of both kinds, both hypogonadism and the common [270] type of impotence, the functional impotence and the psychogenic impotence, and in the common type of impotence it had no effect. In hypogonadism it had spectacular effects in restoring.

Q. Your opinion, then, is based on actual clinical research as well as study, is that right?

A. It is based on clinical observation and it is fortified by publications in scientific literature.

Q. Doctor, again on the basis of the sum total of your knowledge as to this subject, do you have an opinion as to whether the use of the male hormone would relieve and postpone many conditions associated with middle age and improve the sense of well-being?

A. I am not quite sure that I have a correct understanding of "the many conditions associated with middle age." For example—is that what you mean?

(Testimony of Charles Huggins, M.D.)

Q. No. To put it conversely, Doctor, do you know of any conditions normally associated with middle age which will respond favorably to male hormone therapy? A. I know of none.

Q. Do you know whether the administration of methyl testosterone would improve the sense of well-being in otherwise normal persons of middle age?

A. A sense of well-being is, in very large part, a matter of the psychology of the patient. I can very well see how, if a person had confidence in this or that agent, if he [271] was taking this or that, it would in all likelihood make him feel better. Whether the belief was founded on a rational basis or not doesn't make any difference; he would be going to feel better. That is why religion flourishes.

Q. If I may interrupt you there, under those circumstances, would this result of well-being be due to a physiological condition or a psychological condition?

A. It would be due to a psychological condition. If a person were healthy, then it would certainly be due to a psychological condition.

Q. Again on the basis of the sum of your knowledge of this subject, do you have an opinion as to whether the use of methyl testosterone, the male hormone, would constitute an adequate treatment for flushes, sweats and chills, impaired memory, inability to concentrate on activities, a tendency to evade them, nervousness, depression, general weakness and lack of physical strength?

(Testimony of Charles Huggins, M.D.)

A. I, categorically, deny it would have any effect on all of those with the possible exception of flushes, and that is slightly complex. That is a technical term and requires further elucidation.

Q. In what situations might the effect on flushes take place?

A. The ordinary bashful girl has flushes but that type of flush is not germaine to the discussion, in my opinion. [272] Patients, people, most commonly women, after the cessation of female hormone production, get something which is commonly known as flushes, hot flushes, both by physicians and the patients. In these hot flushes the patient has a sensation of a wave of heat passing through the body, followed by profuse perspiration, which he usually removes with a handkerchief or a turkish towel or something of that sort.

Q. May I interrupt you there? You say "he usually removes."

A. That she usually removes. I am glad to be corrected on that because this type of flushes which I have just been discussing, wherein a woman will mop her brow or face, we do not see in men. This, we think, is important evidence that physiologic cessation of hormone production does not occur in the human male.

Q. At any age? A. At any age.

Q. Regarding, again, the aspect of flushes, would there be any possible effect in the case of a castrate?

A. A castrate usually will have flushes, and there methyl testosterone will stop the flushes. A

(Testimony of Charles Huggins, M.D.)

person with hypogonadism usually will not have flushes, and I have never seen a normal person with typical flushes that a menopausal woman has, a woman after the age of approximately 45 to 50, where mensturation ceases, where female sex hormone ceases. [273]

Q. Are you referring to the period which is sometimes referred to as the female climacteric?

A. I am referring to the female climacteric.

Q. Now, Doctor, on the basis of the sum of your knowledge of this subject, do you have an opinion as to whether the use of methyl testosterone would result in improved physical and mental work and exert a tonic action, resulting in renewed vigor?

A. I have never seen any improvement in muscular or mental capacity in a normal male. In hypogonad patients, boys and young men, in whom the testes have never developed, it will cause an increase in muscular strength. Testosterone has no effect on the mind, on mental work.

Q. Would that apply to castrates as well as hypogonads?

A. A person, a castrate, in well-advanced adult life, let us say a male castrate after the age of 30, has no decline in muscular strength. He has no decline in mental ability.

Q. Again on the basis of the sum of your knowledge of this subject, Doctor, do you have an opinion as to whether the use of methyl testosterone would impart a better attitude towards social life and cause nervousness, exhaustion and melancholy to disappear?

(Testimony of Charles Huggins, M.D.)

A. I deny all of those categorically, that is, to state it in better English, I deny the effect of methyl testosterone in alleviating melancholy and these other symptoms that you [274] just read.

Q. Doctor, after these symptoms which we have just enumerated—you mentioned that you are familiar with the symptomatology of a person who is deficient in male hormones. Are these the smyptoms of such a person?

A. They are not.

Q. Do you know whether they are the symptoms through which a normal male will pass in his forties or fifties?

A. A normal male does not pass through the symptoms as a result of gonadial deficiency and so he doesn't have the symptoms anyway.

Q. Are they the symptoms, just generally, of any other diseases or conditions?

A. This is a very complex question. Most patients whom we see with melancholy, lack of concentration and that sort of thing—the physician will find the average patient has it as a result of psychoneurosis or a functional nervous state.

Q. Do you have an opinion, Doctor, on the basis of the sum of your knowledge of the subject, as to whether there is such a phenomenon as male climeractic or male menopause?

A. That has been alluded to and described by some physicians but with this view I am completely in disagreement. I do not believe that there is a male climeractic.

(Testimony of Charles Huggins, M.D.)

Q. What is your reason for that opinion, [275] Doctor?

A. The phrase, "male climeractic" obviously is supposed to be identical with or analogous to the female climeractic in the female. In the female the ovary ceases to produce germinal cells and, second, the production of female sex hormone falls to a very low level or vanishes. The production of germinal cells in the male does not regularly occur, even in a very advanced age in the human male.

Q. Do you mean the cessation?

A. The cessation of production.

Q. Then old males will still produce sperm, is that right?

A. Yes; old males generally have sperms and are capable of becoming fathers.

Q. How about the production of testosterone?

A. The male sex hormone, likewise, while it may be reduced in part in old age, and no doubt is, definitely is produced in a healthy person.

Q. Doctor, some time back you mentioned that there are some beneficial and toxic effects of the use of the male hormone. But prior to that, on the subject that you have just mentioned, where you gave an opinion as to the male climeractic, do you know, as a result of your study, research, conferences, discussions and education, whether your opinion is shared by informed medical opinion?

A. I think that my opinion is shared by many people in [276] this respect, some of whom I would call highly informed.

(Testimony of Charles Huggins, M.D.)

Q. Again relating to the beneficial and toxic effects of the male hormone, in view of the fact that there are such toxic effects, what precautions, if any, are necessary in the use of testosterone?

A. I think that testosterone must always be administered under the supervision of somebody with some knowledge of these matters.

Q. What type of supervision would this be? What must the supervising person do before using the testosterone?

A. Well, the judgment of who shall receive testosterone and who shall not receive it is of very great importance. For example, if some of this material would fall into the hands of a ten or fifteen year old boy, it could do very great damage to him.

Q. What is your reason for saying that?

A. It can so damage the testes that the damage will be irreversible.

Q. The damage in what respect?

A. It can damage the production of the male germinal cells so that a young person or animal will not be able to produce spermatozoa. There will be a long lasting atrophy of the testes.

Q. In a male human of 15 you mentioned——

A. Or 10 or 5. I am talking now about a young person. [277]

Q. —would this have any effect on the normalcy of his sexual urge?

A. It would induce puberty, that is, the development of secondary sex characteristics, prior to the normal time. Whether it is desirable to induce

(Testimony of Charles Huggins, M.D.)

puberty at the age of 5 or 8 is a debatable thing. The fact is that most fathers do not advise giving children methyl testosterone to induce puberty at an abnormally early age. [278]

* * *

Q. Doctor, aside from the aspects of the young male, assuming now an adult using testosterone, what would be the nature of a precautionary step before taking testosterone?

A. Well, an adult who wished, naturally, to continue life with the production of children would have to be warned that with 10-milligram doses of testosterone very likely sterility would result, and with 25 milligrams certainly sterility would result.

The Court: Permanently?

A. No, sir. If he were taking the drug, then it would be permanent. If he were to discontinue the drug, the sterility would last anywhere from six months to some years. I am always alarmed to see young men or men who intend to have a family taking testosterone because it is a very dangerous agent and it will produce sterility in them.

Q. (By Mr. Danielson): Doctor, aside from the aspect of sterility, is there a toxic or harmful effect of testosterone in an adult, in which the aspects of sterility are the most serious?

A. There is a more subtle effect in a normal adult. [279] In a normal adult it will depress the activity of the pituitary gland so, on discontinuing the drug, it will be some months, weeks or months, before the pituitary has sufficiently recovered.

(Testimony of Charles Huggins, M.D.)

Q. I believe you have mentioned that you have had experience with the action or connection between testosterone and prostatic cancer?

A. I have.

Q. Doctor, on the basis of your knowledge of this subject, do you have an opinion as to the incidence of prostatic cancer in men of the age of 50?

A. This subject has been studied very much indeed in the last sixteen years. We know now that cancer of the prostate is the cause of death of 5 per cent of men over 50. It is one of the common tumors that one sees in a clinic, one of the common cancers. We know, further, that the disease is present in a very much larger percentage of patients, in anywhere from 14 per cent to 33 per cent of patients. Coming to autopsy, in males over 50 years of age, small cancers of the prostate are demonstrable.

Q. If you have an opinion, will you state the mortality rate from prostatic cancer in those who have a clinical prostatic cancer, which is diagnosable?

A. Until we did our work, the mortality was 100 per cent from the disease. Now, since we have learned that [280] androgen was a damaging agent to patients with cancer of the prostate and have discovered means of controlling the effect of androgens, the mortality rate has been reduced to 80 per cent. I mean 80 per cent died and 20 per cent apparently have extremely long remissions of the disease.

Q. Do you have any opinion as to what is this

(Testimony of Charles Huggins, M.D.)

mortality rate in the event testosterone is administered?

A. Well, testosterone makes the disease grow at a very rapid rate.

Q. Would that tend to increase or decrease the mortality rate?

A. A patient with cancer of the prostate, taking testosterone, would have a hundred per cent more mortality from that disease. [281]

* * *

Q. (By Mr. Danielson): Doctor, you say you have used testosterone in your practice?

A. That is correct.

Q. What procedure do you follow in administering testosterone?

A. Well, feeling as I do, that we are dealing with something that is not innocuous, but a powerful agent both for good and for harm, we proceed something as follows:

We make sure that the patient realizes that while taking adequate doses of testosterone, he will be unable to fertilize, and warn him accordingly.

Secondly, we try to make sure that the patient does not have a cancer of the prostatic gland. That can be done in two ways, the first way being examination of the prostatic gland through the rectum, by means of the finger palpation of the prostatic gland, and the second is by means of certain blood tests which have been established.

Mr. Elson: I did not hear the last sentence.

(Testimony of Charles Huggins, M.D.)

The Witness: Secondly, because of certain blood tests which have been established to indicate the presence of cancer of the prostatic gland.

Q. (By Mr. Danielson): Doctor, is there any supervision maintained during the continued treatment with testosterone?

A. Certainly. We see the patient at rather close intervals, to make sure that nothing untoward is happening. [282]

Q. Now, that is your opinion of a correct manner of administering testosterone?

A. Well, that is the method that we teach these young physicians.

Q. And do you have an opinion as to whether that opinion is likewise shared by informed medical authorities? A. I think that it is.

Q. Now, to go back one moment, Doctor, you mentioned that the mortality rate in men over 50 years of age, from prostatic cancer, is about 5 per cent of all deaths, and that there is an incidence of prostatic cancer in men over 50 of about 14, 15, 16 per cent. Now, are there any men with prostatic cancers—do you have an opinion as to whether there are men with prostatic cancer who do not die from it and to whom it is not diagnosed?

A. We do, anywhere from 14 to 33 per cent of men over 50 actually have tiny Lilliputian cancers in the prostatic gland which are for the moment inactive and frequently in untreated old men these things remain dormant, never becoming causes of morbidity or mortality. The reason I think that they

(Testimony of Charles Huggins, M.D.)

sleep, lying dormant, is that fortunately in middle aged and older aged people, the male sex hormone level is not at the high level that it is in young adults and we think that nature has provided us with a slowdown mechanism of hormone production, and that these tiny cancers do not become [283] stimulated.

However, they can become stimulated when we increase the hormone content of the body artificially to that of a young man.

Q. What is the result when these little Lilliputian dormant cancers are stimulated? What is the result of that stimulation?

A. Then, the stimulation—it is easy enough to stimulate them, namely, to administer androgen, then they become full grown, flourishing things which spread throughout the body, producing prostatic tissue in bones, in liver, in lungs, in places where it does not belong and these kill the patient.

Q. Now, Doctor, is the use of methyl testosterone in a dosage of 25 milligram tablets, taken daily, adequate to provide this stimulus?

A. Whether it will stimulate all of them, I do not know. I know that 25 milligrams of methyl testosterone daily for some months will stimulate some of them.

Q. And your opinion, is that opinion likewise true in the case of linguets of methyl testosterone, 5 milligrams taken three or four per day?

A. It is true of methyl testosterone taken in 20 milligram doses per day.

(Testimony of Charles Huggins, M.D.)

Q. And would that likewise be true of 10 [284] milligram tablets of methyl testosterone taken three times daily or one time daily for an indefinite duration?

A. Well, with methyl testosterone, 10 milligrams taken three times daily, it would be a very great hazard. With 10 milligrams taken once daily, there would be some hazard, but not nearly as great as with the larger doses.

Q. You have mentioned that you have diagnosed and treated cancer of the prostate and have observed the effect of testosterone on the cancer of the prostate. Can you tell us in general what is the effect of testosterone on cancer of the prostate?

A. Well, it is something that has interested us very much. We found that testosterone made prostatic cancer flourish and that, conversely, removing testosterone made prostatic cancer wither and shrink and disappear.

And the reason it interested us so much was created a little interest in a few places in this country was that removing testosterone from patients with cancer of the prostate, human cancer shriveled up and disappeared, and this was the first instance where it was possible by drugs to cause widespread cancer in human beings to dry up and disappear.

Q. In addition to the use of drugs, are there any methods of removing the testosterone from the body?

A. The best way of removing testosterone from

(Testimony of Charles Huggins, M.D.)

the body of patients with cancer of the prostate is to remove the [285] testes and this little operation which we devised has now been universally adopted. So that some tens of thousands of patients each year are subjected to the operation of castration, to relieve cancer of the prostate.

Q. You mentioned producing the same effect by drugs. Could you explain that, please?

A. Well, if you give the female sex hormone in appropriate dosages, that has the ability of neutralizing the effect of whatever male sex hormones the patient is producing, so it vitiates what testorterone the patient is producing.

Q. How do you know that the use of testosterone actually accelerates or affects the growth of cancer of the prostate rather than it being some other element that produces that effect?

A. Now, we enter the field of clinical investigation. Occasionally we are forced to do things to human beings, in a few cases, to make a few observations that are not strictly in the patient's best interests. We do nothing that will do permanent harm or at least we attempt to, in medical investigation, but we found that the removal of the gonads would cause, in a very spectacular way, widespread cancer of the prostate to shrivel up, to shrink and to disappear.

Then, we had to try the converse and we gave testosterone to patients with mild cancer of the prostate and when that was done, either 10 milligrams of methyl testosterone a day given [286]

(Testimony of Charles Huggins, M.D.)

by mouth or 5 to 10 milligrams to 25 milligrams of testosterone injected, then the patient became very ill, indeed, and had to take to his bed.

Q. And by illness you mean an effect on the prostatic cancer?

A. The cancer became very much more active and we were able to see that because of these blood tests which we had, which showed very well the activity of cancer of the prostate.

Q. Now, Doctor, this effect which you have just now described of methyl testosterone, does that apply likewise to early cancer?

A. It activates early cancer, and in those cases I have seen, it does.

Q. Now, you have mentioned blood tests, Doctor. Would you advise us a little more fully on that aspect?

A. Well, cancer of the prostate forms a product called acid phosphatase. A normal prostate forms acid phosphatase but, when a patient gets cancer of the prostate, under certain circumstances this enzyme acid phosphatase gets into the blood and reaches a very high level and one can measure the acid phosphatase in a patient and make a diagnosis of cancer of the prostate, because when the acid phosphatase in the blood is at a certain level it clearly indicates the presence of cancer of the prostate, and so that this is a rather unique situation. By means of an enzyme in the blood, you [287] can diagnose the presence of cancer and if the

(Testimony of Charles Huggins, M.D.)
enzyme rises, due to some treatment, you know that the cancer is worse.

If the enzyme decreases as a result of another treatment, the cancer is better.

Q. What treatment would produce this decrease in the enzyme?

A. Removal of the testosterone by castration will cause a decrease of acid phosphates and the administration of female sex hormones will cause a fall, an emelioration of the cancer.

Q. And the reason for this latter, the female hormone, the reason it causes a decrease is what?

A. Because it overbalances the normal production of the male sex hormone that the testes is producing.

Q. And tends to be an antidote for the effect of the testosterone, is that correct?

A. Very well stated.

Q. Do you know whether there is any relationship between the presence or absence of testosterone and the presence or absence of the phosphatase in the blood?

A. Yes. When the testosterone is removed, then the phosphatase in most cases of cancer of the prostate comes down to normal.

Q. And if it is again replaced?

A. If it is again replaced, yes. Clinical [288] investigation, because we don't do that any more. It is an anti-social thing to do, in our opinion. Then, the phosphatase goes up and the cancer is worse.

Mr. Danielson: No further questions.

(Testimony of Charles Huggins, M.D.)

The Court: Before cross examination, Doctor, for the benefit of my reasoning in this matter, I would like to follow up on a few matters:

Examination

By the Court:

Q. As I understand, the production of the male hormone is in the testes and the initial source comes from the pituitary gland. A. Yes, sir.

Q. Now, you have told us about some of the ailments that the testes are inclined to, as to what other glands have a relation to it, the pituitary, for insance, is it subject to ailments and disease?

A. The pituitary, sir?

Q. Yes. A. It is.

Q. They affect the production?

A. They do, sir.

Q. What are some of those diseases?

A. Well, the hormones work together as a well balanced team, very much like a team in sports. If they take away one [289] member, all of the members of the team suffer therefrom. Certain children are born with absence of pituitary cells that can stimulate the testes, and they are the children that I mentioned before who had hypogonadism.

Q. Yes. A. That is one of the conditions.

Q. Now, do other glands enter into the performance? For instance, a diseased gall bladder of long standing, would that have any effect on them?

A. No, sir, not unless the patient were very ill.

Q. Well, that would reduce the general vitality?

(Testimony of Charles Huggins, M.D.)

A. Any condition of severe illness with reduction of general vitality reduces the formation of the male sex hormone.

Q. Now, you mentioned two methods of determining if there was a cancerous condition in the prostate, one digitary and the other by blood tests.

A. Yes, sir.

Q. Are there any other tests?

A. Well, these are the most practical methods available. At times one can do a surgical operation and take a biopsy, but that is not a practical test. And actually we have found enough this spring to develop a more highly refined blood test than this phosphatase, so many workers now can tell with a high degree of accuracy the presence of cancer [290] in general in the body. This is another method beyond phosphatase, determination by still a blood method.

Q. These blood tests, do they call for microscopic work?

A. No, sir. It is a chemical determination. It is somewhat analogous to a Wassermann test for syphilis.

Q. With reaction?

A. Yes. It is not strictly comparable, but it is done by chemists in the same way.

Q. Well, an ordinary practicing physician, would he be capable of doing it in his own office?

A. Well, I think not, not unless he were chemically minded, but the average good sized hospital where there is a chemist, they could determine it.

(Testimony of Charles Huggins, M.D.)

Q. From blood specimens? A. Yes, sir.

The Court: I think that is all. I thank you.

Cross-Examination

By Mr. Elson:

Q. Doctor, in discussing this subject, we have to start, in a sense, from what is alleged in the information or otherwise the complaint with which the defendants are charged.

Now, one of the things that is charged is that this product, testosterone, methyl testosterone, 25 milligrams, one tablet daily, is dangerous because it may result in the [291] acceleration of the growth of an incipient carcinoma of the prostate.

A. That is right.

Q. Now, that is the kind of a cancer of the prostate that we are talking about. In your field, that is your specialty, isn't it, urology?

A. That is right.

Q. Well, now, let us think about the average general practitioner to whom a person goes and we will say complains of these various symptoms that Mr. Danielson read to you this morning.

Now, that man is not a physician, is he? He is a general practitioner.

A. That is right, sir.

Q. Isn't it your opinion that if such an individual complained of those symptoms, that such average general practitioner would, in all probability, prescribe testosterone propionate or methyl testosterone in linguets for the individual for a pe-

(Testimony of Charles Huggins, M.D.)

riod of say four to six weeks, and see whether or not those symptoms were relieved without going through the rather elaborate tests that you have described here today?

Do you get my question?

A. All except the average physician. I don't know what an average physician is.

Q. Well, I don't know how I can say it any more clearly. [292]

I am talking about the average type of competent, general practitioner that we will find in the average community.

The Court: An all-around family doctor.

Mr. Elson: An all-around family doctor, yes.

A. Then, I think some of them would prescribe in that way and some would not. I think that very few of informed physicians would.

Q. (By Mr. Elson): And by informed, what do you mean?

A. People who try to keep up with the latest literature, the latest dissemination of knowledge about these things. We have all kinds of people in our field of medicine. Some we are not very proud of and some we are intensely proud of.

Q. I understand that.

A. Well, some people study and learn. I think that the average good physician would not prescribe these things helter-skelter.

Q. Do you mean by that, that you do not believe that even though a man came in and complained of

(Testimony of Charles Huggins, M.D.)

those symptoms, that a good family doctor (we are talking about an average one now)——

A. Yes.

Q. ——not an outstanding one, the average good family doctor, do you think that he would, before prescribing use of this product, first palpate the prostate and then have a blood [293] test such as you have described conducted, to make sure?

A. I think that most of the average physicians would recognize that as no indication for sex hormones.

Q. Well, I don't think that is quite the answer to my question.

A. Well, I beg your pardon. I think the average physician would palpate the prostate but would not do blood tests.

Q. Does the blood test embrace a biopsy?

A. No. It is just a little blood taken from the vein (the witness indicates his left arm) but, as I told his Honor, that can only be done in rather well established hospitals.

Q. So that in your opinion the average doctor of whom we are speaking, and let us put it that way so I won't have to repeat it every time, the average doctor of whom we are speaking, in your opinion, would palpate the prostate to see whether or not he could feel anything abnormal there?

A. I think the average doctor would.

Q. And then, if he found nothing, isn't it reasonable to suppose that he would then prescribe testos-

(Testimony of Charles Huggins, M.D.)

terone, methyl testosterone, let us confine ourselves to that, he might inject it, I don't know, say for a period of four to six weeks and see if the symptoms were relieved?

A. Some of them would, some of the average ones, but I have no way to tell statistically whether 53 per cent of [294] them would or not.

Q. I see. A. I think the average, that——

Q. Let us come back again——

Mr. Danielson: May he finish?

Mr. Elson: Did you finish?

The Witness: I was going to say, by the average man I do not mean any genius, but I consider the average practitioner of medicine a scholar, a student, somebody who tries to keep up with the latest things. I recognize as well as you do that he can read these things in certain text books, that there is a male climacteric, when he doesn't feel so well he ought to take methyl testosterone or testosterone in one way or another, that he might take that. But, for many years now in our medical school and in a number of others, we have taught that these symptoms are the symptoms of being run down, overworked, fatigue, that one can usually accomplish these things usually better by a vacation on the beach than by drugs.

Q. (By Mr. Elson): That is true, that is what you teach in the university. A. Yes, sir.

Q. But isn't it true that the fine technical knowledge that you people are teaching in the university as applied to the subject of urology is not something

(Testimony of Charles Huggins, M.D.)

that is known completely [295] by the average doctor that we are talking about?

A. All of the young medical graduates of the last 10 years have had it.

They get it as a matter of the formal medical course.

Q. Now, with our average doctor that we are speaking of, hasn't it been your experience that he is really quite a busy man?

A. That is right.

Q. Not so much as during the war, but still he is a very busy man? Isn't it true that with such an individual, when he gets through administering to his patients, that there is not very much time for him to sit down and read scientific articles on the mass of subjects that are published pertaining to the human body, that is, prostate, heart, brain, and so on, and so on and so on? A. Yes.

Q. Isn't that true? A. It is true.

Q. Now, isn't it also true that the general practitioner, therefore, to a very large extent, relies upon the information concerning different products that is given to him by the manufacturer of them, in this case such as Schering, Roche-Organon and Ciba, isn't that true?

A. I don't think he relies on it quite as much as might be inferred. The average physician I think while he doesn't [296] have much time to read, has some time to read. I would deny that he had no time to read. I think the average physician reads the prescribed reading, namely, the Journal of the

(Testimony of Charles Huggins, M.D.)

American Medical Association, which practically every physician in the United States gets. This Journal has review articles time and again, ad nauseam, so if he misses it this month, he is apt to get it four months later, and I think the average physician learns in both ways. He learns from every person, doctor, nurse, orderly, medical student, from professors, drug salesmen and patients, in every other way, and also he does some reading. So just where he might get his information I would not be prepared to say. [297]

Q. Now, then, coming back to this incipient carcinoma, we have our average doctor, we will say, who examines a man and finds nothing out of order. "Incipient" in Taber's Medical Dictionary is defined as "beginning." Is it your opinion that, by such method of examination, the doctor we are speaking of would be able to find an incipient carcinoma of the prostate?

A. He can find some of them but not all.

Q. Would you say in the majority of instances he could find them?

A. I think in the minority of instances he can find them.

Q. In other words, isn't this true, that cancer starts from a cell and it multiplies and it has a wild growth throughout the body, which to the present time is uncontrolled, and so, until that cell is multiplied, or has multiplied, many thousands of times, there wouldn't be any physical abnormality of that

(Testimony of Charles Huggins, M.D.)

organ which could be detected by the doctor by that examination, that is, preliminary to stimulation, if it were stimulated by the agents which we know cause it to grow?

A. With androgen, then, in a few weeks, it could very likely be detected.

Q. I understand it is your opinion that, even if there were just one cell there, in your opinion, such a product as this would stimulate it more and more and more? [298]

A. That is my opinion.

Q. But I am talking about whether in its incipient stage the doctor would be able to find something there which would indicate to him a cancer of the prostate.

A. I think that the average physician might be able to recognize a minority of them. He certainly couldn't recognize them if there were one cell or a hundred cells or a thousand cells or a hundred thousand cells. But that is biologically very few because you can develop a hundred thousand cells in a week or two. But with a larger number you could pick them up so you will get a minority of cases. And the better the physician the more he will pick it up.

Q. You have conducted considerable experiments on this subject of the effect of testosterone on the growth of carcinoma of the prostate and you have written several articles on it?

A. Yes.

(Testimony of Charles Huggins, M.D.)

Q. Your first paper on that was about 1939, wasn't it?

A. I think I mentioned it in 1939 but the first formal presentation was 1941.

Q. At that time you were of the opinion that testosterone accelerated the growth of a prostatic cancer and you had no clinical proof of it, is that correct?

A. No, sir; that is not right. Whenever we made that statement, we had proof. I think I have had proof for [299] every statement I have made in medical literature.

Q. I don't have the article right here in front of me but I am referring to reports that others have made concerning reports that, in turn, you have made. A. Yes, sir.

Q. And my remembrance of them was that in that report of yours of 1941 you were of the opinion and suggested that cancer of the prostate was accelerated by testosterone. [300]

None of those articles made the statement that you reported that you had clinical evidence that it was a fact other than a matter of your opinion based upon inferences from other things you had discovered?

A. No, sir; that is incorrect.

Q. It is?

A. Yes, sir. It states categorically, in black and white, in 1941, in our first publication, that we had proof of it.

Q. Will you tell me what actual proof you had

(Testimony of Charles Huggins, M.D.)

from clinical examination that testosterone accelerated the growth?

A. We could follow it by examining the blood, phosphatase enzymes in the blood.

The Court: Will you say that over, Doctor?

A. Yes, sir; phosphatase enzymes in the blood. Here for the first time man was capable of measuring the activity of a cancer by chemical means, which I didn't do. My assistant did it or I would do it and she would get the blood. So the examination was independent of knowing what treatment the patient was getting, how he was feeling, what size the cancer was, and all that. And we had this elegant method—and I hope you will excuse me for saying "elegant"—we had this elegant method, and we could tell the activity of the disease from day to day just as you could tell the activity of an infection by taking a patient's temperature two or three [301] times a day. We could tell whether the cancer was worse or not. And we gave testosterone and the cancer was worse in two or three days. And we would do other things. We would remove the testosterone and the cancer would be better. And that is all in Cancer Research for March, 1941.

Q. Did that appear in the form of a book?

A. Well, it was an article, so to speak.

Q. Where was the article?

A. Cancer Research, Volume 1, Page 293, March, 1941.

(Testimony of Charles Huggins, M.D.)

Q. Cancer Research, Volume 1, Page 293, 1941? A. Yes, sir.

Q. Now, can you state as a fact, Doctor, that the activity of that cancer was not actually caused by something else in the body and then stimulated by testosterone, that is, the effect of putting testosterone into the body, whether its effect upon something else, in turn, affected that and so on? In other words, was it a pathological or physiological condition that caused that acceleration and growth?

A. We were able to convince ourselves that it was the testosterone that did it.

Q. Have you had any more recent tests in which you feel that your conclusion or opinion is fortified? A. Certainly.

Q. And when was the most recent one?

A. I think June, 1949, in Cancer Research, Volume 9, [302] for June, 1949.

Q. With regard to those symptoms that Mr. Danielson read off to you, I believe I understood you correctly to say that, in your opinion, those symptoms or conditions would not be aided by testosterone even though they were the result of a hormone deficiency.

A. I think I must have been very unclear on the matter. Muscular strength and the development of the secondary sex characteristics in young castrates or patients with hypogonadism are helped very much by testosterone.

Q. How about these others, though?

A. Listlessness, lack of memory and those things cannot be helped in any person.

(Testimony of Charles Huggins, M.D.)

Q. Even if they were suffering from a hormone deficiency? A. Quite right.

Q. Did I understand you to say that you did not believe that there was such a thing as the male climacteric?

A. I did, although I qualified it by saying there is a difference of opinion in medical circles. I am certain on the point. There is no doubt in my mind that there is no male climacteric but I can quote some references by people who say that there is.

Q. I notice in the literature that there are a great number of articles in which the male climacteric is discussed. A. That is right. [303]

Q. And I take it you do not share the opinion of those investigators that there is a male menopause or climacteric and so on?

A. That is true.

Q. By the way, isn't it a fact that there is no appreciable hormone storage in the body?

A. Hormone storage is a matter of four of five days only.

Q. Does it last that long?

A. Yes; it lasts four or five days. I agree with you that indicates there is no appreciable hormone storage.

Q. In other words, four or five days you would not consider to be a period that would be long enough to be placed in the category of the secretion being stored?

A. No; that is not appreciable.

(Testimony of Charles Huggins, M.D.)

Q. You spoke of the patients in your hospital. I was just wondering when you were testifying who comes to your hospital. Is it just anybody that wants to come in? A. Yes, unfortunately.

Q. And I suppose that they are people who don't have the funds to go to a regular hospital and pay for it?

A. No, sir; that isn't quite right. The University of Chicago Hospital is owned and operated by the University of Chicago. In order to keep the roof over the heads of the professors, it is necessary for us to charge a fee. So that the [304] patients that we see are private patients in large part and we see charity patients also. But most of them pay for their service.

Q. Is it your opinion that testosterone causes cancer of the prostate?

A. It is not known what causes cancer of the prostate. It is my opinion that it does but that is a qualified opinion. We have no definite knowledge. All I know is that testosterone activates it.

Q. It couldn't very well cause cancer of the prostate, could it, because, if it did, why every normal male would be doomed to die of cancer of the prostate?

A. No; that is not very acceptable reasoning to me. It is my impression that testosterone causes it but we have very salutary mechanisms in the body whereby only one-third of us get it, and we have it 14 to 33 per cent at the age of 50 probably. There are salutary mechanisms whereby the hor-

(Testimony of Charles Huggins, M.D.)

mone level falls 50 per cent and the tumor is not stimulated, but it can be stimulated when we give testosterone.

Q. Your opinion would be, then, that in an individual whose testosterone production did not decrease with advancing years, the testosterone that he produced would cause cancer of the prostate?

A. I think so, but that is just an opinion.

Q. You have no particular evidence to support it? [305] A. No.

Q. By the way, that opinion of yours is not shared by others, is it?

A. Well, I don't know about that.

Q. Pardon me just a moment. Doctor, I have here a September 28, 1946, issue of the Journal of the American Medical Association, and, under "Queries and Medical Notes," on page 252, this question was submitted by a doctor in New Jersey to the American Medical Association for answer. The question was: "A man aged 46 with impotentia coeundi has been administering 25 milligrams of methyltestosterone to himself every other day for the past year with gratifying results. The patient now insists on having a pellet of testosterone propionate inserted in his thigh. Can the administration of 25 milligrams of methyltestosterone every other day be continued indefinitely or could the pellet be inserted without danger of eventually causing cancer of the prostate?

"Answer. Testosterone propionate is probably more effective when administered by injection than

(Testimony of Charles Huggins, M.D.)

when implanted in the form of pellets. There would be no objection to a trial of the material in pellets. The danger of the development of carcinoma of the prostate is no greater with one form of administration than with another.

"Carcinoma of the prostate apparently occurs rarely in a patient who is receiving treatment with testosterone propionate; [306] the medicament may be given when indicated without worrying about its carcinogenic properties. Every patient receiving it should be carefully examined to make sure that carcinoma of the prostate is not present before treatment is started. Under such circumstances the treatment, of course, would not be given. If carcinoma is not present initially, the likelihood of inducing it with testosterone propionate is evidently so slight that it may be disregarded."

Do you share the same opinion as the writer of this answer? Would you like to see this?

A. Yes. Could I look at it?

Q. Yes.

A. As I stated before, we don't know what the cause of cancer of the prostate is. I agree that every patient receiving it should be carefully examined to make sure that cancer of the prostate is not present before treatment is started. The editor says, "If carcinoma is not present initially, the likelihood of inducing it with testosterone propionate is evidently so slight that it may be disregarded."

(Testimony of Charles Huggins, M.D.)

I would disagree with that although, as I say, I don't know what the cause of this is.

Q. By the way, would you think that, if a person were administered an injection of 50 milligrams of testosterone propionate, and then were given 10 milligrams of methyltestosterone, a hundred tablets, to be taken once a day, that [307] there might be—or, in your opinion, would that tend to accelerate the growth of an incipient carcinoma?

A. Yes, sir.

Q. At one time it was your opinion that the method of combating cancer of the prostate was by castration? A. It still is my opinion.

Q. But I think that in your direct examination you stated that you didn't do that now as frequently as formerly?

A. Oh, no. That is the best method of control and we still do that.

Q. Oh, I beg your pardon. I had understood that you had said that you did do it and now you don't do it.

A. No. We have these two methods. The castration operation is more effective than the female sex hormones.

Q. I think you briefly said that—wait a minute. You know Dr. Ira T. Nathanson don't you?

A. Very well.

Q. Are you familiar with his article appearing in the symposium entitled "Recent Progress in Hormone Research, Volume 1, 1947"?

A. No, sir.

(Testimony of Charles Huggins, M.D.)

Q. In that article, entitled "Endocrine Aspects of Human Cancer," he discusses tumor of the breast, cancer of the breast and cancer of the prostate gland and, finally, in conclusion, it is stated as follows: "A considerable number [308] of data bearing on the relation of the endocrine organs to tumors have accumulated. The administration of sex hormones through experimental animals has resulted in the production, the augmentation and the inhibition of benign and malignant tumors. These changes are limited to definite types of tumors in different species, as well as to certain strains in any one species of animal. Thus, there are other factors that determine the reaction of a tissue to a hormonal stimulus, and the susceptibility of an animal to the induction of neoplasm. It is difficult to interpret these facts in terms of human cancer. Nevertheless, they are of extreme importance in the study of the origin and course of cancer in general." Would you share the conclusions stated there by Dr. Nathanson with respect to the causing and acceleration of the growth of a prostatic cancer?

A. I didn't think that he mentioned anything about that.

Q. He was speaking of the cancers he had discussed in his article, one of which was cancer of the prostate.

A. I think animal research has a greater significance toward human problems than he states.

Q. Animal experiments don't mean necessarily

(Testimony of Charles Huggins, M.D.)
you can translate those into the same effect on humans, does it?

A. There are some reservations but, in general, you can.

Q. In experiments with rats, for instance, is it usual to select rats or mice for experimental purposes who are [309] particularly susceptible to cancer? A. Correct.

Q. Is it your opinion, though, that animal experimentation or using animals as subjects can accurately be translated, in so far as cancer of the prostate is concerned, to its effect upon humans?

A. Well, the type of cancer of the prostate that humans have has never been produced in animals.

Q. I wonder if this article here would have any significance to you in connection with what you have just said. It is in the book entitled, "Endocrinology of Neoplastic Diseases." Are you familiar with it?

A. I am familiar with it. What is the date of it?

Q. 1947. On Page 207 the author of the article says, "In spite of the evidence in man that carcinoma of the prostate is improved by orchidectomy, and made worse by the injection of androgens, there are no reports of the production of carcinoma of the prostate in animals by injection of androgens. These studies include those of Rossole and Zahler on adults and of Zahler on senile dogs. In both instances the period of study was relative short and the amount of androgen given was prob-

(Testimony of Charles Huggins, M.D.)

ably inadequate. Zuckerman and Parkes injected 242.5 milligrams of testosterone propionate into a castrated rhesus monkey during 91 days. The histologic structure of the prostate was normal." [310]

If my mathematics are correct, that would figure out about 2.66 milligrams injected every day. Would that have any significance in connection with what you have told us about the effects of testosterone propionate or testosterone accelerating the growth of cancer?

A. No, sir. The fact that it has never been produced in experimental animals, while distressing to a professional investigator like myself, doesn't mean that the thing is hopeless. What we know about cancer of the prostate is as follows: It has never been observed in a castrate man, if a person was castrated in early life for one reason or another. So I know this, that the presence of the functioning testes is essential. It must be there for some years; otherwise no cancer. [311]

* * *

Q. Doctor, eliminating eunuchoids and castrates from consideration, approximately how much testosterone in one form or another do you think that your hospital has prescribed say in the last five years?

A. Well, the only indication we have accepted for those is in the cancer of the breast, in women, where the drug has a different effect than it has

(Testimony of Charles Huggins, M.D.)

in the male. There it causes the cancer to decrease.

Q. Pardon me. I am eliminating women. I am speaking only about men.

A. I don't think we have prescribed any in our hospital.

Q. In the last five years? A. Yes.

Q. Now, on this subject of the male climacteric, you are familiar, of course, with the publication, The Urologic and Cutaneous Review?

A. Yes, sir. [313]

Q. And with Hans Lisser and Robert F. Escamilla? A. Yes, sir.

Q. And they have written for that, as you recall, on some occasions? A. Yes.

Q. Now, I call your attention to volume 46, page 87, of the issue of February, 1942, an article appearing by them, entitled "Testosterone Compounds in the Male. Clinical Indications and Methods of Administration." On page 90 they state as follows, under the subheading "Male Menopause":

"Until recently the male menopause has been ignored except for rather bizarre attempts at rejuvenation by testicular graftings or by tying the spermatic cord (Steinach's operation). Perhaps this neglect was due to the conception that the male menopause consisted merely of the natural diminution and final loss of libido and potency in advancing years. Little heed was given to the less obvious but more important manifestations consisting of mild vasomotor flushes, increasing irritability,

(Testimony of Charles Huggins, M.D.)

failing memory and decreased capacity for mental effort. The customary day's work is not accomplished as speedily, as cheerfully or as effectively as before. We are inclined to believe that during this period conservative androgen therapy is indicated and may be highly beneficial. However, care must be exercised to avoid undue sexual stimulation, especially in men [314] between 50 and 70 years of age who suffer from hypertension or show evidence of arteriosclerosis or myocardial damage."

Are you in agreement or disagreement with the statement of the writers of that article?

A. I am in disagreement with the indications for the drug.

Q. Now, in the same publication, a different volume, volume 50, issue of March, 1946, there is an aarticle entitled "A Contribution to the Endocrine Aspect of the Impotence Problem—A Report of Thirty-nine Cases," by Harry Benjamin, M. D., of New York City. Do you know Dr. Benjamin?

A. I know the name.

Q. In that article he discusses those cases and states as follows, on page 143:

"As for gratifying general results, they were observed in 72% of the cases in the group receiving parenteral treatment, and in 71.4% of the patients who were given methyl testosterone. These figures are in close agreement and indicate that there is no difference in the gneral response irrespective of the compound administered. Improvement of appetite, gain in weight and physical strength, ameli-

(Testimony of Charles Huggins, M.D.)

oration of urinary disturbances and increased memory, endurance, ability to concentrate, etc., were frequently observed in both groups."

Are you in agreement or disagreement with the statements [315] that I have read of the author?

A. In disagreement, sir.

The Court: What was the date of that last?

Mr. Elson: 1946, your Honor, March, 1946.

Q. Now, in the Journal of Urology, volume 49, at page 872 of the issue of June, 1943, is an article entitled "The Male Climacteric: Additional Observations of Thirty-seven Patients, by August A. Werner."

Do you know Dr. Werner?

A. I know the name.

Q. Now, if you will bear with me, if your Honor please, this will be a little bit longer than the others. On page 872 the author speaks, under the subheading of "Subjective Symptoms," he says:

"Since the climacteric is the result of a neuro-endocrine imbalance, it is necessarily functional. The subjective symptoms accompanying gonadal hypo-function render the patient more uncomfortable than do the objective signs. As reported for the female, the symptoms in the male may be classified as (1) nervous, (2) circulatory and (3) general."

Then, dropping down, the writer makes this discussion under those three symptoms that I have just read:

"Nervous symptoms. All patients complained of

(Testimony of Charles Huggins, M. D.)

an intense subjective nervousness, or a feeling of tension. There is a sensation of an inward tremulousness, which usually does [315] not become manifest. This is especially noticeable upon arising during the night or in the morning. Excitement or fatigue accentuate it, and then a tremor may be noticeable, which should not be attributed to hyperthyroidism.

"Nervous people are irritable and they are easily aggravated or excited to anger by word or deed. Noises of playing children, the radio, almost anything stirs them to action. In fact, they need no special stimulus. They are hard to please and frequently the family or associates say that they can hardly get along with them. In many instances they acknowledge this condition, but state that they cannot help being so.

"Excitability is a nervous state in which the persons respond to ordinary stimuli in an exaggerated manner, especially as regards the psychic response. Unfavorable news, slight mishaps, arguments, all manner of little occurrences that would not disturb a normal individual cause quite a nervous and mental flurry.

"A large majority of these patients complain of sleeping poorly. They may be restless, sleeping only for short intervals during the night. Some fall asleep quickly upon retiring only to awaken within one-half hour and remain awake for varying lengths of time. Others do not sleep upon retiring until after midnight. Some complain that

(Testimony of Charles Huggins, M. D.)
they sleep well until 2 or 3 a.m. and then remain awake until morning. [317] Patients who do not sleep at night find themselves exhausted the next day and must sleep during the day time. This desire to sleep during the daylight hours must not be confused with somnolence.

"Formication, a sensation as if ants or insects were crawling over the skin, especially on the back and body, is frequently complained of. There may be itching, prickling or tingling of the skin. Numbness and tingling of the hands, feet, or one or more of the extremities often occurs. Frequently these people awaken while lying in bed and find the extremities completely numb. Some have stated that they had to sit up and rub their arms or legs, and one person awakened and arose to go to the bathroom and fell to the floor because the feet were numb.

"Headaches of various types and location occur, but are rarely migrainous. They may be described as a dull to severe ache, usually not neuralgic, and may occur irregularly or be continuous. Their location may be temporal, frontal, vertex or occipital, with any combination of these. There are two types of headaches which have almost specific diagnostic importance in gonadal hypofunction: viz., vertex and occipito-cervical. The occipito-cervical ache may radiate to the neck, over the scapular regions or down the spine. It may last from hours to several days and when present the patients complain that their mind seems hazy or fogged, and this

(Testimony of Charles Huggins, M. D.)

mental [318] haziness may last for days. The vertex ache is frequently described, as if a great weight were resting on the head, or as a feeling of pressure.

"There is decreased memory and ability for mental concentration. Cerebration is slowed, and they are forgetful, especially for recent events. If they read an article they cannot tell what they have read, and must reread it several times before it registers; names, figures and dates are especially difficult to remember.

"Depression or mild melancholia is an important symptom; when this is present the patients have loss of interest in their work, their home, or in their past pleasurable diversions, they want to avoid people and may cry for no special reason. They realize that there is something wrong within themselves and they become introverts and are ill at ease, have fear of some impending danger and worry unnecessarily. There is a loss of self-confidence and a feeling of futility. At this stage of the condition, these patients verge on psychosis, may be self-accusatory, have thoughts of self-destruction and may actually commit the act. This extreme stage has previously be referred to as involutional melancholia; it is a psychosis, but of definite endocrine origin, as described above.

"Circulatory symptoms. Hot flushes are characterized by a sudden redness of the face and neck, upper chest and at [319] times most of the body. This is akin to blushing and is due to dilatation of

(Testimony of Charles Huggins, M. D.)
the superficial capillaries of the skin. It is a very uncomfortabe sensation, generally of short duration but may last ½ hour or even longer, if the statements of some patients are correct. Frequently this is described as a smothering sensation. They may be accompanied by profuse perspiration. There may be vertigo and scomata or tingling or prickling sensations over the head, neck and body. Occasionally, hot flushes alternate with chilly sensations over the same area or follow them. Hot flushes may accompany disturbances of the cardiovascular system, especially arteriosclerosis with hypertension, but these conditions can be eliminated by proper diagnosis.

"Tachycardia, palpitation and dyspnea, more than usual upon moderate effort, without evident cardio-renal disease is complained of. Walking a short distance, ascending a flight of stairs, almost any moderate effort causes cardiac consciousness. Many of these patients have this group of symptoms occur while sitting quietly or even while lying in bed. At times they are awakened from their sleep by tachycardia and palpitation.

"Vertigo, especially with change of position is often noticed, with no cardiovascular lesion to account for it. Vertigo, tinnitus and scotomata are usually associated symptoms; of these vertigo occurs most frequently. Scotomata may [320] occur as dark, red or silvery specks floating before the eyes.

(Testimony of Charles Huggins, M. D.)

"Cold hands and feet at any season, is complained of by many of these patients.

"The pulse is usually not affected much, unless there is some intercurrent condition and the blood pressure may be increased in an occasional patient.

"General symptoms. Lassitude and fatigability are often present. Some of these people state that there is marked decrease of endurance, they fatigue easily. Others complain that they are constantly tired, or that upon arising in the morning they are unrested or feel more tired than when they went to bed.

"Vague pains are complained of and their location may be as legion as the distribution of the nervous system. However, when a patient complains of pain, one must make a definite effort to determine its significance, before it is lightly dismissed.

"Potency is something apart from libido. Potency is more easily determinable in the male than in the female for obvious reasons. Libido in a large degree depends upon the mental reaction and may be present in the absence of potency. The author has had quite a few women state that libido was more marked during the menopause, then at any other time in their life. This can be easily explained in both sexes because libido operates through the conscious mind. [321]

"Constipation is frequently found in hypofunction of the thyroid and pituitary glands in which we have a relative vagotonia. Many of these patients complain of a gastric syndrome character-

(Testimony of Charles Huggins, M. D.)

ized by distension and eructation after meals with no organic lesions. This is probably secondary to the nervousness and the constipation and usually disappears with sedation and proper elimination. While some cases of constipation may have a glandular basis, the vast majority are probably due to improper habits, diet, gastro-intestinal disease, etc."

Now, are you in agreement or disagreement with the author's discussion of the three symptoms and the sub-symptoms, or the three symptom headings that he classes as associated with that condition?

A. I think they are absurd. I am in complete disagreement.

Q. Now, Doctor, on the subject of fertility——

Mr. Danielson: Is there any explanation that you could make, Doctor, of these symptoms on this particular discourse on this article?

The Witness: If I could speak for about a minute. Due to our treatment, we have had a great opportunity to remove the testes of very many men with cancer of the prostate gland and so that we know from intimate experience what the symptoms of male hormone deficiencies are since removal of the [322] testes is the most drastic type of male hormone deficiency that it is possible to obtain; none of these patients complains of nervousness, tremulousness, irratibility, constipation, insomnia, eructation, scotomata, vertigo, headaches, all these other things. These patients feel well except for one thing, they develop hot flushes and profuse perspiration attacks. These symptoms, it seems to me

(Testimony of Charles Huggins, M. D.)

that these writers have spoken about, we attribute them to fatigue and psychoneurosis and not due to hormonal deficiency because a man completely deprived of testes does not complain of any of these symptoms.

Q. (By Mr. Elson): Now, Doctor, however, the article of the Journal of Urology is considered to be an authentic publication, isn't it?

A. Well, the Journal is usually pretty good.

Q. And it is quite widely distributed to medical men who are interested in that phase of medicine?

A. That is quite right.

Q. Pardon me?

A. I still deny them as taking them as a sign of male hormone insufficiency.

Q. And it is to be found in practically every well-stocked medical library in the country, isn't it?

A. Quite right.

Q. Isn't Dr. Werner considered to be a urologist or a [323] doctor of considerable repute in that field?

A. Dr. Werner is an endocrinologist and he is well known. Let us put it that way.

Q. In other words, you disagree with his statements?

A. I think he is well but not favorably known.

Q. How about Dr. Lisser and Dr. Escamilla?

A. The same.

Q. Now, on this subject of fertility, I am going to do what I did yesterday with counsel's state-

(Testimony of Charles Huggins, M. D.)

ments, and cut our time short and accomplish the same result, anyway.

I have here a little pamphlet that is put out by the Professional Service Division of Ciba Pharmaceutical Company and in that the various statements are made which are reported to be from the literature. In discussing the effect of testosterone propionate and methyl testosterone on the testes, they say as follows, and I am only reading the last sentence, and that is on page 8 of that pamphlet, and the pamphlet number is 108:

"Other authors have pointed out that both number and viability of the spermatozoa can fluctuate during the continued use of androgens or that the cause is usually of minor significance as compared to the enormous improvement obtained in all other respects."

The quote being an article by Dr. Lisser and Dr. Escamilla appearing in the Urology—— [324]

A. Urology and Cutaneous Review.

Q. ——Urology and Cutaneous Review, volume 46, page 87, written in 1942.

Are you in agreement or disagreement with the statement that is quoted of the authors there?

A. If I understand it correctly, my position, I would like to say that—let us begin again. So far as the doses of androgen will cut down the sperm count—the statement that you read to me was rather ambiguous that there were fluctuations in certain patients, but despite those fluctuations, better go ahead with the treatment anyway because of good

(Testimony of Charles Huggins, M. D.)

improvement in the sense of Dr. Lisser and his colleague. But actually the sperm count, provided enough testosterone is taken, goes right down and may reach zero. [325]

Q. But you are not, as I understand it, then, in agreement with their opinion that that fact is of minor significance as compared to the enormous improvement obtained in all other respects?

A. No, sir; I am not because it may be of very great significance if a husband becomes sterile.

Q. Isn't it a fact that the age bracket of most men who take testosterone is generally 45 on up?

A. I know a lot of young people who would take it if they could get hold of it.

Q. I am not going to object to that. It is, obviously, a conclusion. Do you feel there are a lot of young people who would take it if they could?

A. Yes.

Q. Getting back to my question, isn't it true that the majority of people who take testosterone are in the bracket of 45 and up? A. Right.

Q. Now, is it your opinion that men within that age bracket are generally interested in producing offspring?

A. Generally, they are not.

Q. Just one other question. You are aware, aren't you, that hundreds of thousands of packages of testosterone in one form or another are sold by Schering Corporation, the Ciba and Roche-Organon every year; that it may run into the [326] millions? I don't know. A. That is right.

(Testimony of Charles Huggins, M. D.)

Q. Isn't it strange to you, Doctor, that, if what you say is true, that so many men have a dormant prostate cancer and that testosterone will accelerate its growth, the incidence of actually diagnosable prostatic cancer and recognizable distress of the individual because of it, in view of that large quantity sold, it is not greater than it is?

A. I think that 5 per cent of men over 50 dying with cancer of the prostate is a very high percentage as it is.

Q. Then, you attribute that, do you, or would you in part, to the large volume that is sold by these companies?

A. I didn't say that. I think that this is a very common disease. I am impressed by the large amount of it in the American population.

Q. Isn't it your experience that for the most part testosterone throughout the United States is sold on prescription? A. Right.

Q. So that, if testosterone is responsible for a high percentage, as you say, of men dying of cancer of the prostate, then the fault lies with the doctors who administer it?

A. I think that the drug is a very valuable drug, and we must always prescribe testosterone. The only point I have is it must be given under supervision to detect the serious [327] things that happen.

Q. Wait just a moment. I think I am about through. I have no further questions.

(Testimony of Charles Huggins, M. D.)

Redirect Examination

By Mr. Danielson:

Q. I have just a few questions for clarification, your Honor. Doctor, what do you mean by orchidectomy?

A. That is surgical removal of the testes.

Q. And what do you mean by the expression "indications for the drug"?

A. Indications for the drug in the male—the only ones I recognize are hypogonadism and castration, for other reasons than for cancer of the prostate.

Q. Doctor, when an early or incipient cancer of the prostate is diagnosable, is it possible, through male hormone therapy, by periodic regular examination of the prostate, to diagnose a carcinoma of the prostate while it is still small? A. It is.

Q. And while it is still susceptible to rather favorable treatment, is that correct? A. It is.

Q. Doctor, another point, regardless of what an average doctor might do on examining a patient prior to using hormones, or regardless of whether he actually detects an early or incipient carcinoma of the prostate, isn't it a fact that the methyl testosterone would still accelerate such a growth?

A. Certainly. [328]

Q. And on another point, directing your attention to the so-called male climacteric, regardless of whether or not there is such a thing as male menopause or male climacteric, are the symptoms

(Testimony of Charles Huggins, M. D.)

which have been brought into evidence several times the symptoms of a male hormone deficiency?

A. The symptoms described by Dr. Lisser and by these other gentlemen that Mr. Elson read are not, in my opinion, due to a male hormone deficiency.

Q. And next to the last question, I understand the latter part of the testimony was that in the greater portion of the United States these drugs are sold under prescription.

This would indicate, would it not, that such drugs were administered by physicians and under their supervision?

A. That is correct. My point is that this is a very powerful drug and, if it is properly used, it is extremely significant to the community as an important drug.

Q. Under such medical supervision, an early prostate cancer could be detected, is that correct?

A. Yes; in addition to a very dangerous condition later.

Q. And, finally, again, Doctor, assuming a man who has no prostatic cancer or other pathological condition which would be an indication against the use of testosterone, would the use of testosterone produce within him any harmful effects of which he would be personally aware?

A. It might produce harmful effects of which he would [329] not be aware but of which he would be aware after some months or years.

Mr. Danielson: No further questions.

(Testimony of Charles Huggins, M. D.)

Recross-Examination

By Mr. Elson:

Q. Did I understand you to say, Doctor, that practically every state required testosterone to be sold on prescription?

A. I don't know the legal aspects of this, sir. It is my impression that most of the testosterone used in Illinois, for example, is under a physician's prescription.

Q. As a matter of fact, and, if it refreshes your recollection, all right, and, if it doesn't, all right, aren't there only three or four states in the United States that require it to be sold under prescription?

A. I never went into the legal aspects of it, sir.

* * *

The Court: Doctor, would you be able to give us an [330] estimate as to the male population of the country who, at some various times in their lives, are afflicted with flushes and sweating, this long list of symptoms given in this article by the Doctor? Would you be able to state whether there are such symptoms which are common to nearly all of the male population or whether they are sporadic?

A. I think the symptoms are very common, indeed, your Honor; I think very much more common than in people who work under tension, that is, than among people of low intelligence. I think that most intellectual workers complain of one or more of these symptoms sometime in their lives.

(Testimony of Charles Huggins, M. D.)

The Court: It has been mentioned a number of times here about incipient and dormant cancer in the prostate and that it comes from an accumulation of cancer cells, as I understand it. Are cancer cells inherent in the prostate gland?

A. By that do you mean does every man have to have them?

The Court: Are they just there waiting for something to accelerate their growth there?

A. I think that they are in somewhere between one-sixth and one-third of the male population over 50; in the other two-thirds or five-sixths that there are no cancer cells.

The Court: They just naturally are in a large proportion of the population?

A. Roughly, a third of us over 50.

The Court: Is that the favorite spot in the human [331] organism for them to reside?

A. No, sir. Cancer is commoner in both the skin and the stomach and in the human male the prostate is number three.

The Court: I want to ask you another question that might be helpful to me. I have heard it said many times that Vitamin E, which is, I believe, a preparation from wheat, has certain effects. What I wanted to ask you is is there any relationship or any effect of Vitamin E on this male hormone we have been talking about?

(Testimony of Charles Huggins, M. D.)

A. There is no relationship that has been recognized as yet, sir, to the best of my knowledge.

The Court: No relationship or no effect?

A. No, sir, they are two independent things. Vitamin E is essential for the development of sperm, but there is no close relationship and there has been no relationship detected between that and testosterone.

The Court: That is all.

Mr. Danielson: No further questions.

Mr. Elson: I have no further questions.

Mr. Danielson: Dr. Glass, please. [332]

SAMUEL J. GLASS, M.D.

called as a witness on behalf of the government, being first duly sworn, testified as follows:

The Clerk: Your full name?

A. Samuel J. Glass.

The Clerk: G-l-a-s-s?

A. Right.

Direct Examination

By Mr. Danielson:

Q. What is your address, Doctor Glass?

A. My office address is 360 North Bedford Drive, Beverly Hills.

Q. Of what school or schools are you a graduate and with what degrees, please?

A. I have the M.D. degree from the Medical Faculty of the University of Toronto.

(Testimony of Samuel J. Glass, M.D.)

Q. And in what year was that? A. 1923.

Q. What post-graduate training did you have?

A. Three years of hospital work, one year at the University of Toronto and two at the Hospital of the Good Samaritan in Los Angeles.

Q. Are you now engaged in the practice of medicine? A. I am.

Q. How long have you been so engaged?

A. Since 1925. [333]

Q. Do you specialize in any particular field of medicine?

A. I do. I practice a specialty known as endocrinology.

Q. And will you please explain generally what you mean by endocrinology?

A. It is a study and a treatment of diseases emanating out of disorder of the functions of the endocrine glands or those responsible for the internal secretions of the human body.

Q. Are you associated with any local hospitals or clinics?

A. I am with the Cedars of Lebanon Hospital.

Q. In what capacity?

A. I am the Director of the Department of Endocrinology, in which there are three distinct clinics, the general endocrine clinic, the thyroid clinic and the sterility clinic.

Q. Are you a member of any professional societies, Doctor?

A. I am a member of the local Los Angeles County, State and American Medical Associations;

(Testimony of Samuel J. Glass, M.D.)

I am also a member of the American Society for the Study of Sterility; the Association for the Study of Internal Secretions; the Society for Experimental Biology and Medicine; the Association for the—well, I have forgotten the name of the other one. It is too long-winded.

Q. What qualifications are required for membership in the Society for Experimental Biology and Medicine?

A. One must be a qualified investigator in either the [334] medical or the biological field.

Q. Does that include original research, Doctor?

A. Original research must have been done before election to membership.

Q. Have you published in any scientific publications the results of some of your investigations?

A. I have published many reports in many different journals.

Q. Are you familiar with the female sex hormones, Doctor? A. I am.

Q. In your practice, do you make use of the female sex hormones? A. Extensively.

Q. Are they known also as estrogens, Doctor?

A. That is correct.

Q. About how many years have you utilized these substances?

A. Approximately twenty.

Q. Could you tell us briefly in what manners the estrogens can be administered?

A. They may be administered in a variety of routes of administration, orally, hypodermically, by

(Testimony of Samuel J. Glass, M.D.)

pellet, implantation under the skin, and by the inunction or massage into the skin of these various compounds. [335]

Q. What is meant by the term "mixed natural estrogens"?

A. They are natural derivatives or products from the extractions of pregnancy, urine from the mare, or the human, and, also, from the human placenta.

Q. Do they contain estrone, Doctor?

A. In large measure, among other estrogenic compounds.

Q. An estrone is, likewise, a female sex hormone, is it? A. Right.

Q. Is mixed natural estrogen considered to be an effective estrogen? A. Yes.

Q. Can it be administered in the same manner as these other estrogens? A. Yes.

Q. That is, it can be rubbed onto the skin and absorbed? A. Yes.

Q. Is this considered an effective route of administration?

A. It is not popularly or commonly used as a good method of administration.

Q. Can its efficiency be compared with oral or subcutaneous administration?

A. That varies with the medium in which the hormone is present, whether it be in an alcoholic tincture or whether it be an ointment base, and the character of the ointment [336] would change its absorption but approximately 20 per cent can be

(Testimony of Samuel J. Glass, M.D.)

absorbed from an ointment base through the skin.

Q. Have you had personal experience in this route of administration? A. Yes.

Q. For what conditions have you administered estrogens through the skin, that is, by rubbing them into the skin?

A. There are two common conditions which have warranted the use in my experience, the use of topical application of estrogens in under development in the female breast and superfluous hair in females who manifest a tendency to a masculine beard, for example.

Q. Have you used the estrogenic material in this manner for the purpose of enlarging human female breasts? A. Yes.

Q. And, on the basis of your professional training, education, your study and your experience, do you have an opinion as to whether it is possible to enlarge the female human breast by applying estrogens directly to them?

A. I believe it is possible.

Q. Doctor, I show you a copy of Government's Exhibit No. 3, a label relating to Menformon Dosules, and ask you to read that label to yourself. Here is the original document, which you may read a little more easily.

A. Yes; it is a little faint. [337]

Mr. Danielson: May the record show this is Government's Exhibit No. 3?

Q. Assuming that the product referred to in

(Testimony of Samuel J. Glass, M.D.)

that label is the composition which is declared on that label, is it a mixed natural estrogen?

A. Yes.

Q. Are you familiar with this preparation?

A. Yes.

Q. Do you mean you have had personal experience with it? A. Yes.

Q. For what purpose did you use it, Doctor?

A. I tried it out in a number of patients for the specific purpose of enlarging the underdeveloped female breast.

Q. Your experience for this purpose would include about how many applications of this drug, in round numbers?

A. Oh, I remember this firm having sent me a couple of hundred of these dosules for clinical trial, a good many years ago; the exact time I don't remember. I used them all without result, without good results.

Q. On the basis of your training, education, and the sum of your knowledge of this subject, do you have an opinion, Doctor, as to the efficacy of a product such as Menformon Dosules described in Government's Exhibit No. 3, their efficacy in enlarging the breasts of women?

A. I found this particular product to be of no value [338] for that purpose.

Q. Doctor, now I refer your attention to Government's Exhibit 3-B, a circular which accompanied this product, and I call your attention to the last page thereof, where the following statement appears: "Breast Development. Direct Action on

(Testimony of Samuel J. Glass, M.D.)

the Mammary Gland. Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce characteristic stimulation or mammary growth, and the result is definite breast growth of considerable degree. Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hyposmastia presents a valuable addition to the physician's therapeutic resources. 25 days supply, 50,000 International units, $7.50; 25 days supply, 125,000 International units, $14.00." Doctor, on the basis of your professional training and experience, your education and your studies and research, would that statement be true as applied to the product described in Government's Exhibit 3, the Menformon Dosules?

A. That dosage would be inadequate in my experience. [339]

Q. (By Mr. Danielson): Doctor, have you had experience with other estrogenic preparations of same or greater potency for this same purpose?

A. I have.

Q. For example?

A. Well, I have used products of similar composition, but with estrogens in the range of five to twenty times greater than these specified in the pamphlet and the label of the dosules.

Q. And likewise, for the purpose of enlargement of the breast? A. That is correct.

Q. And what were the results achieved with this preparation, the stronger preparation?

(Testimony of Samuel J. Glass, M.D.)

A. They were good in a very selected small group of women under observation, namely, those who were young, usually under 20, who manifested hormone deficiency in terms of ovarian function, so that not only were the breasts underdeveloped but their genital tracts were similarly underdeveloped. So that those women with hormone deficiency did respond to the topical application of estrogens to the breasts.

Q. Were there any successful results where there was no hormone deficiency?

A. None whatever.

Q. Do you have an opinion, Doctor, as to the incidence [340] of hormone deficiency in females?

A. Only an approximate idea. I would say in the range of 10 or 15 per cent of the women who present themselves to me, either at my clinics or in my private office, would have or would manifest a hormone deficiency.

Q. Only, that is, of those who present themselves?

A. That is right.

Q. And does that presuppose anything? In presenting themselves, is that any indication that they feel there may be something wrong?

A. Exactly. They present themselves to me because they are seeking help in overcoming.

Q. Then, this ten to fifteen per cent would not apply to women in general?

A. Not at all.

Q. Now, Doctor, if a woman has a small bust, does

(Testimony of Samuel J. Glass, M.D.)

that mean that she is suffering from a deficiency of her own hormones? A. Not necessarily so.

Q. Would you explain that, please, Doctor?

A. Well, nature endows us with a variety of shapes and sizes of different organs. Very much like the size of one's nose or the shape of one's foot, it is not necessarily dependent upon the sex hormones for its ultimate development. There are many women who have perfectly normal reproductive function and yet have very small breasts. Yet, those breasts may suckle, may develop adequate amounts of milk, and after nursing they may regress to their original small size. So that size alone is not necessarily a sign of failure of function. It may be a cosmetic defect but not necessarily a functional failure.

Q. Will you kindly explain, Doctor, what you mean by cosmetic defect?

A. Well, American civilization especially seems to emphasize the importance of cosmetic perfection in terms of a female bust. It is advertised, very widespread, in that regard. I think the American women particularly are self-conscious about the size and shape of their breasts.

Q. Now, Doctor, converse to your previous explanation, would it be true that a woman who is deficient in her natural estrogens likewise would have a small breast?

A. Those who are deficient may or may not manifest a small underdevelopment of the mam-

(Testimony of Samuel J. Glass, M.D.)

mary glands. They frequently do have small breasts, not necessarily so.

Q. Then, there is no direct relationship between the two phenomena? A. No.

Q. How, in what manner is it possible to determine whether or not a female human has a hormone deficiency?

A. That can be determined by the investigation of the [342] individual from many different aspects aside from the usual inventory of the patient's history, her development, her feminil background, there are certain physical stigmata that are demonstrable by physical examination, and likewise certain laboratory tests will reveal hormone deficiencies.

Q. Now, in those tests and in these matters of diagnosing a female hormone deficiency, do they require any special training, Doctor?

A. Very much training.

Q. Are there any subjective symptoms by which a woman could correctly diagnose her own female sex hormone deficiency?

A. I know of none.

Q. Now, Doctor, in your work as an endocrinologist, do you use an estrogenic substance known as alpha estradiol? A. I do.

Q. Do you consider this to be a potent substance? A. I do.

Q. Are you familiar with the use of a tablet in the strength of .5 milligrams per tablet?

A. Yes, I use such tablets.

(Testimony of Samuel J. Glass, M.D.)

Q. You have used them, you say?

A. I mean I have prescribed them.

Q. Do you know whether there are any dangers in the use of such a tablet?

A. Very specific dangers. [343]

Q. What are these dangers, Doctor?

A. The first and perhaps the most important is that of impairment or disturbance of the menstrual cycle in the female, and in so doing I believe that fertility will be impaired likewise. Secondly, there are certain females who actually manifest some degree of intoxication by an intoxication of the female hormone, literally intoxication, so that they are very uncomfortable and made sick by the hormone, and there are many manifestations of that particular intoxication. It is a broad interpretation of what happens from overdosage.

The other very distinct hazard of that is that of stimulating in the sensitive female patient various types of new growths in the female breast, in the uterus, not necessarily malignant growth but benign growths. I believe that estrogens, like the prostate in the male, will manifest acceleration of growth of any tumor, whether it be benign or malignant under the influence of estrogens over a long period of time.

Q. By a malignant tumor, would that include a carcinoma, Doctor? A. Exactly.

Q. Have you seen any such cases of acceleration of the growth of carcinoma, Doctor, in a female?

A. I have seen three.

(Testimony of Samuel J. Glass, M.D.)

Q. And how do you know, what causes your opinion that [344] this acceleration was due to the use of a female hormone?

A. Two of these patients were seen in consultation, consultation having been solicited by other physicians who gave me the history that these patients had taken estrogens over a long period of time, either by prescription or by self medication, the exact details of which escape me at this moment.

A third patient was under my own supervision during the time that she was taking estrogens and a carcinoma seemed to develop under my very own eyes.

Q. This carcinoma had some different appearance from a normal carcinoma, is that correct, Doctor?

The Witness: Your question is a little ambiguous. Just what do you mean?

Q. (By Mr. Danielson): How is it possible to determine that this has developed in a manner that is often normal, other than the normal development of such a carcinoma?

A. It is impossible to be too certain as to whether the carcinoma would have manifested itself with or without the added estrogen. It is impossible to be certain of it. But this much is true: that clinically and experimentally, it has not been possible to observe the development of cancer in the absence of estrogen; that is important; that the female who is a castrate or without ovaries will never manifest malignant growth in the bust or in the uterus if she

(Testimony of Samuel J. Glass, M.D.)

did not have it before castration. The same thing is true of the experimental animal. You cannot induce experimentally cancer growth in the experimental animal, in the absence of estrogen or ovarian activity.

Q. In your opinion, Doctor, the presence of estrogen is a condition precedent to any development of such a malignant growth?

A. It is an absolute prerequisite.

Q. Doctor, just for the sake of clarification, is the uterus a part of the female generative system?

A. A most important part.

Q. Now, Doctor, do you use estrogens in your practice? A. Extensively.

Q. Now, under what circumstances do you find that it is safe to use them?

A. Well, the first requisite is the presence of a hormone deficiency, an estrogen deficiency, and assuming that that is already present, a great deal depends upon the age of the female, whether she be in the reproductive age or whether she be in the menopausal age, because the mode of administration under those circumstances is widely different. So that the age of the patient and the condition of the patient makes all the difference as to how you give it and how much you give.

Q. Would you explain that a little more fully, Doctor?

A. All right. In order not to disturb the fertility or [346] menstrual function of a female in

(Testimony of Samuel J. Glass, M.D.)

her reproductive age, the estrogen must not be given continuously, because by the continuous administration of estrogen you interrupt the normal sequence of events that make up the monthly rise and fall that constitutes the menstrual cycle; and unless you more or less stimulate the natural sequence of events in terms of rhythmic rise and fall of estrogens, along with other hormones, such as progesterone, you will not serve your patient in any useful function.

Q. Does that require careful supervision, Doctor?

A. All of that implies the most meticulous diagnosis and supervision.

Q. In such hormone therapy, is it desirable or is it necessary to first eliminate the possibility of present cancer?

A. It is most important to eliminate that possibility, by the most careful search for any type of tumor, growth in the uterus or in the breast, because I have already indicated that estrogens will accelerate the growth of benign or malignant tumors in these organs.

Q. Over how long a period should this supervision, continual supervision, take place?

A. As long as the patient requires treatment.

Q. And what is the purpose of that continuous supervision, Doctor?

A. Obviously to prevent the interruption of the reproductive function; secondly, to avoid intoxica-

(Testimony of Samuel J. Glass, M.D.)

tion, and thirdly to avoid the stimulation of tumor growth.

Q. In other words, if such a growth were to appear, then, what action would be indicated?

A. Obviously estrogenic treatment must be stopped immediately.

Q. Will you explain a little more fully what you mean by intoxication, in this connection?

A. Well, there is a very complicated aspect of treatment. Many women present themselves already overloaded, if you will, with ovarian hormones, particularly the estrogens. I have done a great deal of research on the importance of the liver, for example, in terms of estrogen metabolism; in the presence of liver disease the estrogens are not eliminated in a normal fashion from the human body; they pile up, so to speak, in the blood and give rise to what is known as hyper-estrinism, that is, an excess of the hormones. This excess of estrogen will of itself lead to various types of intoxication.

Q. May I interrupt you one moment. Are you referring now to the woman's own natural supply?

A. Her own natural estrogens. I was coming to the point of the artificial administration.

Mr. Elson: Pardon me for a minute. Is that in issue here?

The Witness: No, I was just coming, Mr. Counsel——

Mr. Danielson: Just a moment. He is just

(Testimony of Samuel J. Glass, M.D.)

explaining [348] the term intoxication which has been put in.

Mr. Elson: That is all right. It doesn't make any difference to me, except if we are going to inject something else, some other condition that can be caused by this, other than what is put in the information, well, we are getting into an issue that isn't in the case which means that we unnecessarily prolong it, don't you think?

Mr. Danielson: Well, we will not pursue the point any further, your Honor. No further questions.

Mr. Elson: Could we have a short recess, until we gather some things together?

The Court: Yes.

(Whereupon a short recess was taken.)

Mr. Danielson: Your Honor, with the permission of counsel there is one additional question I would like to ask.

The Court: Yes.

Q. (By Mr. Danielson): Doctor Glass, you have testified as to the effect of 0.5 milligram tablets of alpha estradiol. Do you have an opinion as to what would be the effect of the administration of tablets containing .1 milligram each of crystalline alpha estradiol in this dosage, three daily for ten days and one daily thereafter?

The Witness: Well, the word "thereafter" will have to be qualified.

Q. (By Mr. Danielson): Then, one daily, without the word [349] "thereafter."

(Testimony of Samuel J. Glass, M.D.)

The Witness: ——as to what duration of time the tablet will be taken will make all the difference, as to whether it constitutes a hazard to the patient or not. The dose is relatively small. On the other hand, the human economy is so constituted that there is a great deal of variability as to the response to these artificial hormones. Some respond very well to a small dose. Others require larger doses. So that everything would depend upon the actual status of that individual, as to whether the .1 milligram tablet will constitute a hazard or not. If that individual is a healthy individual and is free of cancerous susceptibility, then, administration of that kind of estrogen or that dose of estrogen over a short period of time may do no harm. Over a long period of time, it may do considerable harm.

I wonder if that is what you wanted?

Mr. Danielson: Yes, I believe that it is. No further questions.

Cross-Examination

By Mr. Elson:

Q. Doctor, you just stated that alpha estradiol in the quantities mentioned by Mr. Danielson would do harm with some women and with other women it would not. The same thing really is true, isn't it, with something that is more simple and associated with our daily life, for instance, Coca-Cola to a person who has diabetes and does not know [350] it?

A. It is a poor analogy, but I think it is acceptable. The diabetes might be impaired all the more by too much sugar.

(Testimony of Samuel J. Glass, M.D.)

Q. And the same would be true, wouldn't it, with butter?

A. Depending on what we are talking about.

Q. Well, a diabetes?

A. Oh, that is a debatable point. A good deal depends exactly on how that butter would be applied and in terms of relative proportion to carbohydrate and protein in the diet.

Q. Well, now, I do not mean to get into the discussion of diabetes, but I just simply wanted to bring that out at that point.

Now, isn't it true that the same analogy can be applied in the case of many other drugs than alpha estradiol, that are commonly and regularly sold over the counter without prescriptions, depending on the individual and some latent condition within him? A. I don't quite see your point.

Q. Well, let us take a rather humble example, but we have used it before, Bromo-Seltzer. Bromo-Seltzer, as we know, is sold over the counter, it is dispensed by the soda fountain man at the soda fountain, but it is true, isn't it, that a person who becomes addicted to the use of Bromo-Seltzer suffers, can suffer serious consequences?

The Witness: May I make a humble confession? I don't know what is in Bromo-Seltzer. [351]

Q. (By Mr. Elson): Bromides.

A. Bromides—well, bromide intoxication from that kind of a beverage would be a very, very rare complication or very rare end result.

Q. Isn't it a fact that there are people who are

(Testimony of Samuel J. Glass, M.D.)
today mentally deranged, though they may not be in an institution (some may, I don't know), from the overindulgence of bromo-seltzer?

A. I am not aware of it.

Q. Well, isn't it *a true* that a person who overindulges in the use of alkaline products such as alka-seltzer can in time develop alkalosis?

A. It is rather rare, very rare.

Q. Well now, let us come back to our estrogens. Isn't it a very common thing, maybe not in your practice but let us say, take the general average competent practitioner, in other words, the family doctor, isn't it a very common occurrence for women who come to him and complain of conditions, I don't know whether they are necessarily associated with menopause or not, but they complain of conditions in which he determines that estrogen is the thing that he should give them and so for a short period of time he injects them with estrogen, and thereafter puts them on a maintenance dose of tablets and gives them a prescription, and they go back to the drug store, time after time, time after time, and have the [352] prescription refilled without obtaining a new prescription from the doctor?

A. I wasn't aware of the fact that a patient is regularly apt to refill her prescription without further consultation with her doctor.

Q. Well, of course, we will assume that the patient will periodically, not at any stated intervals, return to the doctor for one reason or another, but

(Testimony of Samuel J. Glass, M.D.)

not go to the doctor every time that the box has become empty and she wants it refilled?

A. That is conceivable.

Q. Now, you stated that—I believe I am correct and, if I am wrong and if I am misquoting you, you can let me know, but I thought I heard you say that you had practically seen a breast cancer develop under your eyes from the administration of estrogens? A. Yes.

Q. Have you ever definitely and absolutely, not as a question of opinion or conclusions from other things, but absolutely demonstrated as a fact that the administration of estrogens caused an incipient carcinoma of the breast, cervix or uterus to accelerate in growth?

A. I believe those three instances of my own personal experience were vivid enough to emphasize the possibility that estrogens accelerated the growth of cancer. [353]

Q. In other words, then, it results to this, does it not, that it is from your experience, it is your opinion that possibly cancer of the breast, cervix or uterus results from the administration of estrogens? A. Correct.

Q. Well now, in this case here, we have to come back to the allegations that are contained in the complaint or in the information and those allegations are substantially this: that 5/10 of a milligram of alpha estradiol may accelerate the growth of an incipient carcinoma of the breast, cervix or uterus. Now, Taber's Dictionary defines incipient as be-

(Testimony of Samuel J. Glass, M.D.)

ginning. Do you think that you would be able to diagnose an incipient cancer of the breast, cervix or uterus, find it?

A. Of the cervix and the uterus, perhaps. Of the breast, less likely.

Q. Now, Doctor, you are familiar, are you not, with the manufacturers of hormone products in this country, Roche-Organon, Schering and Ciba?

A. I am.

Q. Now, I think the dosules that you looked at that is on the label were .002 units, were they not?

A. 2/10 of a milligram, approximately that.

Q. Now, it is true, isn't it, that those three firms maintain extensive research and control laboratories, as far [354] as you know?

A. I believe they do.

Q. And, so far as you know, the men who comprise the staff are considered to be competent men in their field? A. The staff of——

Q. In the laboratories of those large organizations?

A. I think that is a safe assumption.

Q. It would be a reasonable assumption?

A. Yes.

Q. Now, Doctor, I am going to show you here a brochure, I guess that is what you would call it——

A. Right.

Q. ——that has to do with the dosules, the label of which you looked at this morning, and there are two pictures on there that show conditions before and after treatment with those dosules. The after

(Testimony of Samuel J. Glass, M.D.)

picture shows a considerable increase in the size of the breast, does it not?

I take it from your testimony this morning, however, that it has not been your experience that dosules of the potency described on that label produce the results shown on that picture?

A. That was my experience. If I may qualify——

Q. Surely.

A. I indicated in my response to the former counsel's last question that there is a great deal of varibility in the [355] response to hormones, no matter how administered. Some individuals respond very well to a small dose. Many others do not. That particular illustration is of one of those individuals who is particularly sensitive to low-dosage hormones. [356]

Q. Well, wouldn't the same thing be true with aspirin? Aspirin will relieve some people of headaches and won't relieve others of headaches and, when one is not relieved by aspirin, he doesn't take aspirin any more, does he?

A. If that is a proper analogy—I think it is a poor one, a very poor one.

Q. Well, go ahead and think so.

A. I have an answer for an analogy like that.

Q. Counsel read to you from the pamphlet that accompanied this dosule and I find in this brochure of which I speak the following statement: "The clinical value of cutaneous estrogen therapy for the

(Testimony of Samuel J. Glass, M.D.)

treatment of underdeveloped breasts was confirmed by C. M. MacBryde, J. A. M. A., 1939, volume 112, page 1045. He states that 'Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth,' and the result in his cases was 'definite breast growth of considerable degree.' Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hypomastia represents a valuable addition to the physician's therapeutic resources.''

Now, I am going to ask you, although I don't need to ask you because it is self-evident, but I would like, for the benefit of the court, to read again what Mr. Danielson did, and you will find that the language is exactly the same: [357]

'' 'Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth,' and the result in his cases was 'definite breast growth of considerable degree.' Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hypomastia represents a valuable addition to the physician's therapeutic resources.''

Doctor, do you disagree with that statement insofar as it applies to the use of dosules such as described on that label?

A. That requires a qualified answer, counsel. I, too, have made the observation as MacBryde, but

(Testimony of Samuel J. Glass, M.D.)

you failed to mention MacBryde uses doses far in excess of that which is possible to obtain from the dosules. You also failed to mention that these women were utterly deficient in estrogens; that they were hypogonadal females, lacking hormone, and thereby benefiting from hormone when administered through the skin or by needle or by mouth. That type of a female may respond, depending on the dose and on the degree of the hormone deficiency.

Q. Then, it would be your opinion that the language that I have just read to you, quoted from the brochure by Roche-Organon, was not a correct statement insofar as it applied to the dosules which were the subject of the brochure? [358]

A. It was an incomplete statement.

Mr. Elson: I think we might as well offer this in evidence now as our first exhibit.

Mr. Danielson: No objection.

The Clerk: Defendants' Exhibit A in evidence.

(Said document so offered and received in evidence was marked Defendants' Exhibit A.)

Q. (By Mr. Elson): By the way, Doctor, you said, I believe, in your direct testimony that you used potencies and dosules 20 times that mentioned on the label? A. Occasionally.

Q. In other words, that would be what?

A. 10 milligrams to the gram. I have even gone as high as 20 milligrams to the gram.

Q. Incidentally, to avoid my taking the time to

(Testimony of Samuel J. Glass, M.D.)

look it up in the dictionary, what is "hypoplesia"?

A. A lack of development.

Q. I have here a book with which you are undoubtedly familiar, "Endocrinology of Women," by Hamblen. A. I am familiar with it.

Q. The date of it is 1945. And, on page 526, chapter 50, under the head of "Tumorigenesis," the author states as follows: "The suggestion has been offered that breast carcinoma results from carcinogenic action of intrinsic estrogens, probably concomitant with functional alterations in the endocrine [359] system. Unopposed or continuous estrogens acting upon responsive tissue may cause a typical cell growth.

"Numerous clinical reports have suggested the possible etiologic importance of estrogens in carcinogenesis but in none has this relationship been proven."

Then there is a description of three cases, and the author continues:

"These three reports are of minor import when one considers the thousands of women who have received estrogens for as long or longer periods of time and in comparable or larger doses without developing carcinoma."

Are you in agreement or disagreement with the statements of the author?

A. You make many statements there. I would like to take it piecemeal, if I may.

Q. Surely.

(Testimony of Samuel J. Glass, M.D.)

A. I disagree heartily with the idea. Three cases of cancer are of no significance as a possible complication of estrogenic treatment. I do agree that in proper dosage, when properly indicated, estrogens may be of value in development of the female breast. What other aspects of the question are there?

Q. I think that covers it. By the way, do you know of the author E. C. Hamblen?

A. He is a personal friend. [360]

Q. He is considered to be an authority in the field of endocrinology, I take it?

A. Female endocrinology.

Q. By the way, it isn't at all uncommon for you folks, just as lawyers, to disagree on various subjects from time to time in their various phases?

A. That is correct.

Q. I have here a book entitled "Recent Progress in Hormone Research," volume 1, a symposium, in which one of the contributors is Dr. Ira T. Nathanson. Are you acquainted with him?

A. I am familiar with the work.

Q. Dr. Nathanson's article is entitled "Endocrine Aspects of Human Cancer," which was published in 1947. He covers tumors of the breast, carcinoma of the breast, tumors of the uterus, cancer of the cervix, tumors of the prostate gland, cancer of the prostate gland and tumors of the testes and so forth, and, finally, on page 281, under "Conclusions," he states as follows:

"A considerable number of data bearing on the

(Testimony of Samuel J. Glass, M.D.)

relation of the endocrine organs to tumors have accumulated. The administration of sex hormones to experimental animals has resulted in the production, the augmentation and the inhibition of benign and malignant tumors. These changes are limited to definite types of tumors in different species, as well as to [361] certain strains in any one species of animal. Thus, there are other factors that determine the reaction of a tissue to a hormonal stimulus, and the susceptibility of an animal to the induction of neoplasm. It is difficult to interpret these facts in terms of human cancer. Nevertheless, they are of extreme importance in the study of the origin and course of cancer in general."

Are you in accord or not with the conclusions there stated by Dr. Nathanson, after having covered the subjects I mentioned?

A. I think it is a reasonable personal interpretation of the known facts.

Q. By the way, when was it that you made those observations as to the development or growth of a breast cancer as a result of the administration of estrogens? A. I didn't say as a result.

Q. I didn't mean to misquote you. When was it?

A. Within the last 15 years.

Q. Can you tell me within what portion of the 15 years?

A. I would say two of those were approximately 15 and 12 years ago and the third was approximately 7 or 8 years ago.

Q. Just a minute. Oh, yes; one other thing.

(Testimony of Samuel J. Glass, M.D.)

It is a fact, isn't it, that during pregnancy a woman produces more [362] estrogen than she does when she is not pregnant? A. That is true.

Q. And, as the period of pregnancy continues on, she produces more estrogen? A. Yes.

Q. Do you find the incidence of breast cancer to be present—that isn't exactly what I want to say——

A. Higher incidence?

Q. ——of breast cancer of higher incidence in women who have borne a number of children or who have borne only a few?

A. If you don't mind, counsel, the question is a little bit ambiguous. Are you implying that the concentration of estrogens during pregnancy may be a factor or may not be a factor? What are you driving at?

Q. I am not trying to be smart with you at all, Doctor. I would like to have you answer the question and then let me go from there.

A. I don't think you have stated it quite clearly enough. If you hadn't added the number of pregnancies or the nursing or what have you—just simplify the question for me, if you don't mind.

Q. Do you find that the incidence of breast cancer is higher with women who have had a number of children than it is with women who have had no children, we will say? [363]

A. I am not sure. My impression is that it is. But one very important aspect of the problem is

(Testimony of Samuel J. Glass, M.D.)

this, that during pregnancy it is a common observation that cancer of the breast grows very rapidly and for that reason women with any cancer susceptibility in their history, or who have had a cancer removed, are always forbidden to have more children.

Q. You are acquainted with Dr. Macdonald out at USC, aren't you? A. I know him.

Q. Ian Macdonald? A. I know him.

Q. Yesterday I asked him the same question and he said that the incidence of breast cancer——

Mr. Neukom: Will you refer to the record?

Q. (By Mr. Elson): On page 142 of the transcript, I asked Dr. Macdonald this:

"Q. Well, do you find in your experience that the incidence of breast cancer is greater with women who have had no children, or women who have had some children or women who have had a lot of children, or just what?

"A. I have statistical information on that subject. The incidence of cancer of the breast is distinctly greater in those women who have not borne children, or who having borne children have failed to nurse them at the breast."

Would you agree with that statement? [364]

A. That might have been his experience. I do not claim any special experience with pregnancy because I don't see pregnant women.

Q. Did I understand you to say that there was clinical evidence, with which you were acquainted, that 5/10 of a milligram of alpha estradiol would

(Testimony of Samuel J. Glass, M.D.)

cause the acceleration of an incipient breast cancer?

A. No specific evidence to that particular dose. I think the general statement would cover it that, having cancer, that individuals manifest acceleration in the growth of that cancer if given estrogens over a long period of time.

Q. That, of course, presupposes a cancer and one which you have been able to diagnose as a cancer?

A. Yes; I know, because early cancer is difficult of detection.

Q. And an incipient cancer of the breast, keeping in mind our dictionary definition, would rarely be designated by you?

A. It frequently escapes detection.

Mr. Elson: I have no further questions.

* * *

Redirect Examination

By Mr. Danielson:

Q. Doctor, what is the meaning of [365] etiologic or etiology? A. Cause.

Q. Causes? A. Causes.

Q. Doctor, is it your opinion that the estrogens will cause the carcinoma of the breast, uterus or cervix, or that they will accelerate their growth, that is, is the estrogen carcinogenic?

A. Estrogen is carcinogenic in certain animals. It has not been proven to be so in the human subject. However, it will definitely accelerate the growth of existing cancer.

(Testimony of Samuel J. Glass, M.D.)

Q. Doctor, the remaining question is, directing your attention again to Defendants' Exhibit A, the brochure from Roche-Organon relative to the menformon dosules, counsel has read therefrom what purports to be a quotation from the Journal of the American Medical Association, 1939, volume 112, at page 1045, as follows:

" 'Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth' and the result in his cases was 'definite breast growth of considerable degree.' "

Now, Doctor, I invite your attention to this article by Dr. MacBryde in the former-quoted entry in the Journal of the American Medical Association, at page 1049, the fourth [366] paragraph of the left-hand column, and will read the remainder of that quotation:

"It is definitely not recommended that this method be adopted in general practice until further studies can be done and the limitations and possible dangers of the cutaneous application of concentrated estrogens can be defined."

Now, Doctor, in view of the balance of this quotation, do you now disagree with Dr. MacBryde?

A. I do not.

Q. And in the same article, in the initial paragraph, on page 1045, I read as follows:

"I have been unable to find records of carefully

(Testimony of Samuel J. Glass, M.D.)

controlled studies of human breast growth. I, therefore, performed studies on three women lacking mammary development and exhibiting signs of marked hypogonadism. In the first part of the study, the hormones were administered by subcutaneous injection. I was able to demonstrate that, by the injection of from 15,000 to 35,000 international units of estrone or of estradiol benzoate per week, active mammary growth could be produced in patients who previously had no visible or palpable breast tissue."

Doctor, in view of that, do you now disagree with Mr. MacBryde on that point?

A. I do not disagree.

Q. And does it conform with your experience in this matter, [367] Doctor?

A. Completely.

Mr. Danielson: Thank you. No further questions.

Your Honor, may we have this exhibit marked for identification as Government's Exhibit No. 17? It is a photostatic copy.

Mr. Elson: As far as I am concerned, you can put it into evidence.

Mr. Danielson: Thank you. We will accept that.

The Court: Very well: It may be admitted.

The Clerk: Exhibit 17 for the government in evidence.

(The document so offered and received in evidence, was marked Government's Exhibit No. 17.)

(Testimony of Samuel J. Glass, M.D.)

The Court: I feel sure that counsel will not object to this, in going outside of the issues here, but it seems to me necessary to inquire all I can as to the nature and the operation of estrogens.

Doctor, I believe it is so that compounds containing estrogen are put on the market, or at least in circulation, for the purposes of ointments for skin treatment?

A. Yes.

The Court: Ointments recommended for face wrinkles and that sort of thing?

A. Yes.

The Court: That is so? [368]

A. That is so and, while the concentration of those estrogenic creams is very, very small, thereby the hazard of this self medication is reduced considerably.

The Court: Does that contain the male hormone or the female hormone?

A. Usually the female, and designed for the cosmetic trade.

The Court: What about the difference, whether they contain the male or the female hormone?

A. A great deal of difference, your Honor. The use of a male hormone preparation in the form of an ointment would actually lead to certain masculinization of the female if the concentration was adequate.

The Court: And what then would be the effect on the female along that general line? It wouldn't affect the male, would ti?

(Testimony of Samuel J. Glass, M.D.)

A. It would affect her adversely if the concentration were sufficiently high to make a difference in the circulating hormone balance.

The Court: Would you say that those creams are in any manner efficient in producing the effect that is sought to be secured?

A. I don't really know, your Honor, because it has been my impression that the concentration of the commercial creams sold over the cosmetic counter is very poor; that it [369] is very poorly concentrated with the hormone. They have so little that I question the value of them for anything.

The Court: That is all.

Mr. Danielson: No further questions.

Mr. Elson: I have no further questions.

* * *

(Whereupon an adjournment was taken until 10:00 o'clock a.m., July 5, 1949.) [370]

* * *

ELMER BELT, M.D.

recalled as a witness on behalf of the government, being heretofore duly sworn, testified further as follows:

* * *

Cross-Examination

By Mr. Elson:

Q. Doctor, you spoke of the Belt Urological Group. Just what is that?

A. They are a group of us working together,

(Testimony of Elmer Belt, M.D.)

all devoting our time to urology. Our offices are at 1893 Wilshire Boulevard in Los Angeles and 120 Lasky in Beverly Hills.

Q. You spoke in your direct examination of the acid phosphatase test. Would you do it, Doctor?

A. Could I do it?

Q. First, how do you spell it?

A. A-c-i-id P-h-o-s-p-h-a-t-a-s-e.

Q. You spoke of that test being a blood test, I think. [372] A. That is right.

Q. That is used for determining the presence of cancer of the prostate, am I correct? A. Yes.

Q. And, as a matter of fact, though, isn't that test of value only when the cancer is metastasized to the bone?

A. It is not clear that it is only when it has metastasized to the bone but certainly it seems to be more definitely positive when metastases have occurred generally and particularly to the bone.

Q. I have here a couple of text books, with which you may be familiar. "Metastasized" means what, for the record, please?

A. It means little groups of cells have sailed over in the blood stream and growing independently of the original source. It could be lymphatic it has gone through and they could float in the peritoneal fluid.

Q. But "metastasized" means ordinarily that it has attached itself to the bone in some way?

A. No; that is not correct. The bone might have escaped. It doesn't necessarily mean that it

(Testimony of Elmer Belt, M.D.)

has attached to the bone. Metastases may extend to other regions than the bony framework.

The Court: Is that applicable to any other kind of cells or germs other than cancer? [373]

The Witness: We speak occasionally of metastatic spread of infection.

The Court: That is what I meant.

The Witness: Yes.

The Court: "Metastasis" means a group moves outward?

The Witness: That is right; that it has left the original site and has gone elsewhere.

Q. (By Mr. Elson): In other words, it has left the prostate and gone to other parts of the body?

A. Yes; that is right. It is possible, however, to have a rise in acid phosphatase in cancer of the prostate with only the local area involved.

Q. I have before me here a book entitled "Clinical Biochemistry," by Cantarow and Trumper, Third Edition. Are you familiar with that?

A. No.

Q. It was published in 1945. And, on page 201, at the bottom of the page, the author states, "Serum acid phosphatase determinations have been shown to be of clinical value only in carcinoma of the prostate, with metastasis." Do you agree or disagree with the statement of the author?

A. That is not wholly in accord with my experience but nearly so.

Q. During the course of this testimony we have referred to Volume 1, "Recent Progress in Hor-

(Testimony of Elmer Belt, M.D.)

mone Research, Proceedings [374] of the Laurentian Hormone Conference." Are you familiar with that work?

A. I am familiar with the Laurentian Conference but I haven't seen their reports.

Q. The Laurentian Hormone Conference is one of the top organizations or groups of its kind in connection with hormone investigation, is it not?

A. Yes, sir; that is right.

Q. Do you know Dr. Ira T. Nathanson?

A. I don't know him; no.

Q. Do you know of him?

A. I have heard of him; yes.

Q. He is considered to be one of the top cancer men in the country, is he not?

A. I am not acquainted with him but he has the reuptation.

Q. In this volume, which apears to be a symposium, is an article entitled "Endocrine Aspects of Human Cancer," by Ira T. Nathanson. In that he discusses carcinoma of the breast, tumors of the uterus, cervix, of the prostate gland, and cancer of the prostate gland. Will you read, on page 281, the Conclusions there? Will you read that, please, and then I will read it for the record.

A. Do you want me to read here?

Q. Just read under "Conclusions." [375]

A. Shall I read it out loud?

Q. Yes.

A. "A considerable number of data bearing on

(Testimony of Elmer Belt, M.D.)

the relation of the endocrine organs to tumors have accumulated. The administration of sex hormones to experimental animals has resulted in the production, the augmentation and the inhibition of benign and malignant tumors. These changes are limited to definite types of tumors in different species, as well as to certain strains in any one species of animal. Thus, there are other factors that determine the reaction of a tissue to a hormonal stimulus, and the susceptibility of an animal to the induction of neoplasm. It is difficult to interpret these facts in terms of human cancer. Nevertheless, they are of extreme importance in the study of the origin and course of cancer in general.

"Strong evidence exists to indicate that endocrine factors are associated with some human tumors. There is as yet no conclusive proof that these influences are directly concerned with cancer, although an increasing number of cases are coming to light in which cancer developed after intensive estrogen therapy in organs such as the uterus and breast, which are normally stimulated by these hormones. It is possible that this is coincidence, but the association cannot be ignored. Present evidence suggests that the sex hormones are not in themselves carcinogenic. It is likelier that, as [376] a result of execessive stimulation of a typical metabolism, the tissues of susceptible persons are conditioned to the action of a carcinogenic agent.

"The administration of hormones or the alteration of the hormonal or metabolic status of the host

(Testimony of Elmer Belt, M.D.)

by castration may exert a profound influence on cancers of the breast and prostate glands. The fact that alterations occur should lead to intensive investigation regarding the mechanism of regression and progression in these tumors. The concept of autonomy of the cancer cell in general must be revised in light of these recent observations.

"There is no question that castration or hormonal administration have been of great benefit, as an adjunct to the treatment of a number of advanced cases of cancer of prostatic or mammary origin. Such treatment should be reserved for palliative purposes only, since there is at present no substitute for established methods in the operable patient. There is little to support the therapeutic value of castration or hormones in any other type of cancer." [377]

The Court: Who wrote that and when?

Mr. Elson: Dr. Ira T. Nathanson, in 1947—or 1946.

Q. Do you agree or do you disagree with the statement of Dr. Nathanson?

A. In general, that sounds like good sense.

Q. You are familiar, of course, with the volume known as "New and Non-official Remedies?"

A. Yes, sir.

Q. And it is true, isn't it, that that is a standard work that is accepted by doctors as a standard work on the subject of the remedies and the drugs that are contained in the volume?

(Testimony of Elmer Belt, M.D.)

A. It is a ready means or quick reference and available guide on drugs which have not yet become definitely standardized in use.

Q. And it is true, isn't it, that that book is published and revised from time to time by the Council on Pharmacy and Chemistry, of the American Medical Association? A. That is right

Q. And it is true, isn't it, from your experience and contact with other doctors, that it is relied on as authoritative?

A. Yes, but it is understood that it is always behind really accepted therapy; I mean in arrears; not yet caught up with. [378]

Q. Doctor, have you examined in "New and Non-official Remedies," the volume of 1948, the subject of "Testosterone?"

A. No; I haven't had occasion to consult that.

Q. I am going to show you "New and Non-official Remedies, 1948," commencing at page 410, and going over to page 411, discussing testosterone propionate and methyl testosterone and ask you if, after having read that, you find any contra-indication in there for the use of testosterone in cases of prostatic cancer or the like or anything else.

A. Your question regarding this was what?

Q. After having read that, do you find any contra-indication in the volume concerning the use of testosterone, in any form, in the case of cancer of the prostate in any stage?

Mr. Neukom: That speaks for itself.

The Witness: No; this doesn't purport to discuss

(Testimony of Elmer Belt, M.D.)

cancer of the prostate and it doesn't mention it.

The Court: It is really silent on the matter?

Mr. Elson: That is correct.

The Witness: Yes. It has a description of the drug and its method of administration and the dosage.

Q. (By Mr. Elson): Isn't it true that in many instances contra-indications are mentioned in that volume concerning drugs? [379]

A. Yes; in that volume and in that paragraph it mentions the contra-indication of destruction of the tubular epithelium and the production of azoospermia.

Q. And what is azoospermia?

A. It abolishes sperm from the ejaculate, sperm being the male sex cell which fertilizes the female, and in one paragraph it says that in young individuals the use of that material destroys that function temporarily. [380]

It doesn't happen to mention cancer. Those men who write that don't purport to set up all of the factors surrounding each of these drugs. If they did, it would take a volume of that size to cover the field of each one.

Q. The portion you speak of covering azoospermia is as follows: "However, continued administration of testosterone may induce azoospermia even though no mention of permanent supression has yet appeared?" [381]

A. Yes; that is right. But in that they are

(Testimony of Elmer Belt, M.D.)

mistaken. Evidence of permanent suppression has appeared.

Q. Doctor, is there any test for the purpose of detecting an incipient cancer of the prostate?

A. An incipient cancer?

Q. Yes.

A. Well, let's cralify what you mean by "incipient."

Q. I don't know, Doctor. I am using the language that is contained in the information or the complaint here. It is charged that testosterone may accelerate the growth of an early or incipient cancer of the prostate. And, in looking up "incipient" in Taber's Dictionary, it defines it as "beginning." That is about as far as I can go. That language has been chosen by the government. And I would like to know from you if you know of any test whereby an incipient cancer of the prostate can be detected.

A. Well, a beginning cancer would indicate that it has already begun and there are tests which show the presence of a cancer of the prostate if it has already begun.

Q. The acid phosphatase test?

A. That would require having the prostate cancer progress to a greater extent than can be determined by other tests, namely, merely simple palpation of the gland across the rectum——

Q. Pardon me for interrupting you. If you did find [382] it on palpation of the prostate, it would no longer be incipient, would it?

(Testimony of Elmer Belt, M.D.)

A. It might be considered incipient or beginning because you can get around it and cut it out and stop it. In other words, it is not ended. To continue with your first question, you were speaking of tests. There are two tests which are already known but not in current use for very early cancer. Charley Huggins has one, which is a test of the proteins of the blood serum.

Q. How recent is that test?

A. He announced it about two months ago and it is not yet in current use. And then at Birmingham another one has been developed. By "Birmingham" I mean the local military hospital here in Southern California. These two tests are closely correlated and they resemble the Wassermann test in their reaction. They are specific protein reactions and they don't show cancer only but other devastating diseases. Their effective use clinically will come about because only when these other diseases are pretty well advanced and therefore recognizable do they affect the test in the same way that cancer does. We are looking forward with much hope to these tests but that is for the future.

Q. Assuming that a man let us say in middle age, 45 or 50, came to a general practitioner and stated that he was troubled with sweats, nervousness, and he didn't seem to remember [383] things like he used to, that he couldn't concentrate on activities, and he always seemed to have a tendency to evade them, and so on, and the doctor was of the opinion, after these symptoms were told to him.

(Testimony of Elmer Belt, M.D.)

that testosterone might be of benefit, what, in your opinion, would the general practitioner do before prescribing testosterone to this man for such symptoms?

A. Well, in the first place, he would think.

Q. Pardon me?

A. In the first place, he would be very apt to think about the problem and, if he thought about the problem very much, he probably wouldn't prescribe testosterone for those symptoms.

Q. Why?

A. Because they don't indicate hypogonadism.

Q. Is it only in hypogonadism that testosterone, in your opinion, is effective?

A. Virtually only.

Q. Hypogonadism, again, is what?

A. A reduction in the amount of testosterone created by the individual, below the level of his needs.

Q. Is it your opinion that testosterone is not of benefit to men, we will say, in that general age bracket, who have complained of those symptoms?

A. I would think it might even be harmful because it [384] would put their trust in a remedy which was not effective and probably would not strike at the source of their trouble. A very careful analysis of that problem would be needed for that patient and he would be very apt to get it at the hands of an alert general practitioner. Probably he was overworked.

Q. Isn't it a fact it is common practice, though,

(Testimony of Elmer Belt, M.D.)

among general practitioners at least, to prescribe testosterone for a man who complains of those symptoms and prescribe it for a period of say three or four weeks and then wait and see whether or not the man has been relieved?

A. I think that would be a pretty loose method of detecting it, although it might happen in the welter of a day's work. I can imagine that a man might take that shortcut but, if he really thought about the problem and got down to business and studied it, he would be concerned, first, about the psychic factors in such an individual and, second, whether he is overworked or not and troubled. Those are psychogenic symptoms you are relating when they relate to men.

Q. Do you think that a general practitioner would conduct any tests, though, before prescribing this for him?

A. If he decided on the use of testosterone for such an individual, would be conduct any tests?

Q. Yes.

A. The thing he would do, most certainly, is make a digital examination of his rectum and feel the back of his [385] prostate because, if there is a malignant process there which he could recognize, he would certainly fan it into a general fire and spread it by the use of testosterone propionate, and I think he would be somewhat reprehensible, at least not acting in accordance with the general custom of the day, if he didn't do a rectal.

(Testimony of Elmer Belt, M.D.)

Q. Would he make any blood or urine tests or anything like that?

A. For that specific question, "May I give testosterone to this patient with a certain degree of safety," there would be no blood test that he would need do unless he wished to do the acid and alkaline phosphatase test. The urine test wouldn't show him anything unless he wished to take the time to give a test for what we call the 17 ketosteroids. The 17 ketosteroids are put out by a male in a certain definite amount and we can measure that amount and determine whether he is suffering from hypogonadism.

Q. Do you think that good practice would require such a man to determine by the 17 ketosteroids test whether the man was suffering from hormone deficiency?

A. Certainly good practice would but he wouldn't be too reprehensible if he didn't do that. If he really wanted to find out if the man had hormone deficiency, that is what he would do and also the acid phosphatase test for cancer of the prostate. The acid and alkaline would show because they [386] are both involved. There are two separate tests there done up in the same bundle. But it is quite probably that, if the general practitioner decided that this was quite likely a hormone deficiency that the individual was suffering from, he would do a rectal examination and then proceed with the use of his testosterone in that individual.

Q. And then wait and see whether or not those

(Testimony of Elmer Belt, M.D.)

symptoms that the man complained of were relieved?

A. Well, he would see that they were not relieved.

Q. He what?

A. He would see that they were not relieved, and then he might begin to think about the problem. But that isn't, in general, the way our general practitioners go about their work. They generally try to solve the problem first and then apply therapy to it. There are so many things you can apply in this modern-day medicine that, if you start out and say, "I will try this drug and the other drug to see which one clicks with this patient,"—the thing to do is to take a history and make a physical examination and determine for what reason this was being used, or I mean what material should be used, and use it with some semblance of reason. Actually, that is the way most doctors think.

Q. However, the general practitioner, of course, would not approach the problem with the same precision that a man who was a specialist in that field would, would he? [387]

A. That problem is the specialty of the general practitioner that you are posing there. You are presenting a middle-aged man who is tired and worn out and who has come to the doctor for some help. That is the general practitioner's meat. He sees that every day, and he must help that fellow. Otherwise, his standing in the neighborhood would drop and he wouldn't have the reputation that he wants

(Testimony of Elmer Belt, M.D.)

in the group he is serving, and, if he prescribes an expensive remedy, and it doesn't do the patient any good, there is a doctor across the street.

Q. In other words, the approach of the general practitioner to the problems of the patient is quite different from the approach of a professional investigator or researcher?

A. I am confused by your question. The researcher is doing research on a problem and his approach is not the clinical approach necessarily. Is that what you are saying?

Q. Yes.

A. But, when he has a patient before him, then he is a clinician. For instance, in our group we are doing a considerable amount of research on a specific problem but we don't see every patient, that comes into our office, in the light of that problem. And that is the way of a research individual who is also treating patients.

Q. In your direct testimony the other day, the following question was asked of you at page 247, commencing with [388] line 12, "You feel that such precautions are a prerequisite to any testosterone therapy then, is that correct?

A. That is right except in groups where cancer of the prostate is not liable to occur and by that I mean the cases in which testosterone is particularly valuable, or the groups of young individuals who show a definite endocrine deficiency in regard to testosterone and who need the substance in the normal process of their growth and development."

(Testimony of Elmer Belt, M.D.)

Now, I was wondering, when I read through that, what you meant when you said—well, I will show it to you. There is the question at line 12 and also down in here. I was wondering what you meant when you said, "I mean the cases in which testosterone is particularly valuable." [389]

The Witness: Well, I think we had already talked about the boys who had their testicles blown off in the war.

Mr. Elson: I don't know whether that preceded that or not.

The Witness: I don't know. Then, following immediately, you went right on and developed that point.

Mr. Elson: I did not.

The Witness: Yes.

Mr. Danielson: I believe if the witness could see the bottom of page 246, the paragraph immediately preceding would be more intelligible, probably.

Mr. Elson: All right. I think it started at line 21, don't you?

Mr. Danielson: Well, the bottom part of 246.

Q. (By Mr. Elson): Will you read that on through there, Doctor, over on to page 247? Then I would like to know what you had in mind.

A. "During the last war, we had a large group of fellows who lost their testicles from land mines. On land mines they stubbed their toe——"

Mr. Elson: No. Turning back to pages 246 and 247, which precedes that.

(Testimony of Elmer Belt, M.D.)

Mr. Danielson: Let us say line 17 at page 247.

Mr. Elson: Line 17 at page 246. [390]

The Witness: "Q. You have mentioned that you have used methyl testosterone or testosterone in some of your treatment. Are there any instances that you know of in which methyl testosterone or testosterone can have a good effect?

"A. There are many instances in which it is a drug" of great value.

Now, you want to know what case it is valuable in?

Q. (By Mr. Elson): Yes. You said by that you mean, there at lines 14 and 15 on page 247, the cases in which it is particularly valuable. What cases did you have in mind in which it is particularly valuable? A. Hypogonadism.

Q. What type of individual is included in that category?

A. Well, individuals in which the doctor feels that the testicles are not performing their proper function, supplying an adequate amount of testosterone.

Q. Would that be the individual whose testicles had not descended or developed as a normal person's would?

A. It is not used in undescent of the testicles, because really you can't feel the—an undescended testicle may be out of reach of palpation, you don't know how big it is or how well it is performing its function from judging by its size, it would not strictly mean undescended testicles; it would mean unde-

(Testimony of Elmer Belt, M.D.)

veloped testicles and undeveloped genitalia, [391] and, given a young individual whose testicles are not up to standard, up in size and whose function is not up to standard and size, a careful administration of testosterone will increase the size of the testicles and of the penis. There is a certain penalty which is paid for that. As you know, bone growth is not complete in youngsters. They are developing in youngsters as they advance. Now, this bone growth will develop despite the fact that the child does not have adequate testicles. As a matter of fact, sometimes it develops that by testosterone propionate given in those early years, it will cause a fixation of the bone growth and we have a young individual who is stunted in his height and length of his arms. So, all that kind of thing has to be taken into consideration and the judgment of the doctor applied as to how much he wants to stimulate the testicles and how much he wants to retard the bone growth.

* * *

Q. It is true, isn't it, that you encounter from time to time young men or boys who have no growth of hair, we will [392] say that they have reached the age when they should have——

A. They have reached the age when they should have and they don't have it.

Q. (Continuing): ——and they don't have it; there is very little pubic hair, is that correct?

A. That is right.

Q. We will say there is little or no trace of any

(Testimony of Elmer Belt, M.D.)

hair on the body such as you might expect with the normal male; would a person like that be included in the class of a hypogonad?

A. Of course, what you really mean is that the sexual distribution of hair is lacking.

Q. Yes, secondary sex characteristics, would that be right?

A. Yes, other than hair growth, because it is another type of alopecia generalis, a case of general baldness.

The Court: Just a moment. Hasn't race and climatic environment much to do with that matter?

The Witness: Yes.

The Court: In the growth or development of hair on the male body?

The Witness: That is right.

The Court: Take the Indians.

The Witness: That is right.

The Court: Take the Eskimos; take people of the tropical [393] regions, they don't have hair on their bodies as the Caucasians and the others do. Take the Ainus, one of the islanders of Japan in the north, they are as hairy as a dog. Do you mean that this matter of hormones has anything to do with the difference between those people?

The Witness: I don't think so. No, not in that sense. I don't think the sex hormone determines racial differences of that type, but I was taking it that way. I think that his question eliminated that feature.

(Testimony of Elmer Belt, M.D.)

Mr. Elson: It did.

The Witness: For instance, a Negro does not have hair, the colored man has wool and his wool is distributed quite peculiarly, you don't find it on his forearms and on his chest the way you do on the white man and, as you say, the Ainu grows in the same territory as his Japanese brother, and the Japanese find it difficult to grow a beard, whereas the Ainu grows one down to his knees and he is proud of it.

To be sure, with hypogonadism, one of its indications is failure to grow hair, at the time when hair should appear, and testosterone propionate could be expected to stimulate the growth of hair in those individuals. It might not.

Q. (By Mr. Elson): Now, these blood tests and the urine tests to determine whether or not there is a hormone deficiency—not the blood test but the urine test to determine, I take it, whether or not there is a hormone deficiency and the [394] acid phosphatase test, the blood test to determine whether or not there is a cancer of the prostate that can be detected, how long do those tests take to complete?

A. The acid phosphatase test, if you are set up for it, you can complete in just a few minutes. It does not take very long.

With the 17 ketosteroid test, in the first place you have to collect a 48-hour specimen of urine, so there is 48 hours.

In the second place, it takes the chemist another two days to do the test and then he has to get his

(Testimony of Elmer Belt, M.D.)

report to you, so you have to allow a week for that.

Q. But the blood test takes how long, you say?

A. Just a very short time.

Q. The general practitioner, I take it, is not equipped to make either of those tests, is he?

A. No, no.

Q. As a rule?

A. No, he is not. As a matter of fact, in our very extensively laid out office, we don't do the 17 ketosteroids. At present, we are sending them over to Cal Tech.

Q. Now, you also stated in your direct examination, on page 253, lines 4 to 12, "There are a few special cases in which testosterone propionate is stimulating and of value over short periods of time, and that applies to methyl testosterone taken by mouth, too." What did you mean; what did you include [395] in those special cases, Doctor?

A. Well, I am not sure that what I am about to say would be generally recognized as good practice, by everyone who has thoroughly studied this problem, but what I had in mind there and what I believe myself, personally, from my own observations, is in regard to several definite symptom complexes. Now, every physician is constantly making observations which are different from those of his fellows, and that is what makes medicine grow.

A little while ago, Dr. Hans Selye of Montreal, in his experimental laboratory, showed that testosterone propionate caused a very good growth of epithelium in nephritis, in cases in which the kidney

(Testimony of Elmer Belt, M.D.)

was robbed of some of its secreting service by disease, that testosterone propionate helped this kidney to come back to function. He carried that work into the clinic from his laboratory, where the observation had been made that an animal given testosterone propionate immediately after poisoning with mercury bichloride, deliberate poisoning to damage the kidney, that the animal would require twice as much mercury of bichloride to cause its death if testosterone propionate were used as an antidote for the poison afterwards. So, picking up that little bit of information that Hans Selye put out in his experimental laboratory work, we applied it further in nephritis cases and found that these young nephritics who were just beginning to show manifestations of nephritis, a [396] disease in which the kidney is poisoned by some poisons in the body little understood, that these patients did very well with testosterone, in fact much better than the controlled cases which were treated alongside of them without it. So I had that in mind. Now, that has been verified in the literature. Other men have noticed it, but in general it is not used for that purpose probably because of its latent dangers.

Now, another group of cases in which we use testosterone propionate, for short periods of time and under controlled observation, is with the elderly man in hospital who becomes disoriented and wakes up in the middle of the night and can't recall where he is and gets up out of bed and is apt to walk down the corridor with nothing on or get into bed with

(Testimony of Elmer Belt, M.D.)

someone else, and who is mentally disturbed. That isn't funny. That is a tragic circumstance. Now, I think it is valid to use testosterone propionate in that kind of a condition. We use other measures, too. We have them breathe oxygen for 20 minutes before they go to sleep, to thoroughly oxygenate their tissues. That is general practice—that is common practice. Testosterone propionate is not used commonly for that, but we use it for that.

Another condition in which we have noticed improvement are these indolent ulcers, of the age in which the leg, the lower leg, has ulcers in it which do not heal up despite everything you do; we find that in a short period of time testosterone [397] propionate brings about sufficient regrowth of tissue to heal over those ulcers. I think that is an observation that is common to many physicians.

Those were some of the things that I was thinking of when I made that statement.

Q. (By Mr. Elson): Now, coming back here to the practioner to whom a man comes, and we will say a man in middle life, and complains of these symptoms that we have mentioned before——

A. You mean hot flashes in a male, a male who is tired, who doesn't sleep or is excessively worried and feels that he is not sufficiently combative?

Q. Yes. The doctor gives him a rectal examination, is unable to detect the presence of anything suspicious from the standpoint of cancer of the prostate, he prescribes methyl testosterone for the man, and the man goes out and fills the prescrip-

(Testimony of Elmer Belt, M.D.)

tion; it is a fact, is it not, that that man can go back to a drug store as often as he desires and have that prescription refilled, without going to that doctor or to any other doctor and having a new prescription made up for him?

A. Yes, in California that is a fact. Now, that is not the only fact. He doesn't have to have a prescription in the first place.

Q. Well, that is true, too. [398]

A. It is true, too.

Q. But even where he has gone to the doctor and the doctor has told him that he will prescribe, and he does prescribe, methyl testosterone for him, the result is just as I have said, he can go back and have it refilled as often as he wants to, without ever seeing another doctor?

A. That is right. That is the grave danger.

Q. Now, on page 253, lines 7 to 12——

A. Or the doctor could circumvent that, if he wished, by just putting a little phraseology on the bottom of the prescription, "Don't Repeat."

Q. Is that common?

A. I suppose it isn't. The doctor forgets to do it. The druggist isn't bound to observe it. Now, what is it you want me to see?

Q. Wait just a minute. Let us pursue that just a little bit further.

Now, then, Doctor, you know of course that the man can have this refilled. Is it common practice for the doctor to state on his directions to the druggist that this product shall only be taken for a

(Testimony of Elmer Belt, M.D.)

certain period of time, in order that any untoward effects from it may be diagnosed by the doctor?

A. No. That would be extremely uncommon practice. What the doctor would do is he would write at the bottom of the prescription, in Latin, "Do Not Refill." [399]

Q. And that is not common?

A. Well, I don't suppose it is. It is not common enough. Sometimes the doctor explains these matters to the patient and obtains their sympathetic understanding of their problem, but there again you are up against the difficulty that even the alert patient does not understand everything the doctor tells him. It is common experience for a physician to patiently explain a problem to a patient and have him fail to understand it.

Q. At page 253, line 7, you said, "What I am pleading for in this case is that it be adequately controlled," that is, testosterone, "with careful observations, in order not to run the patient into danger, because the good advantage this material does is out of all proportion in relation to its harm. The amount of potential harm it has is much more than the good it can do if used unbridled."

Now, what you had in mind there, when you said what you were pleading for in this case, is that the requirement be made that this product be sold only on prescription? A. Yes.

Q. Now, you know of Roche-Organon Company, do you not? A. Yes, indeed.

(Testimony of Elmer Belt, M.D.)

Q. Do you know of Ciba Pharmaceutical Company? A. Yes.

Q. And the Schering Corporation? [400]

A. Yes.

Q. By the way, as a matter of fact, Schering Corporation is owned and operated by the United States Government, isn't it?

A. My goodness, I did not know that.

Q. Isn't it one of the companies that had its origin or control with the I. G. Farben Company in Germany taken over by the Alien Property Custodian?

A. It seems to me that I read something of that sort, but you are far beyond me there.

Q. Now then, Doctor, so far as you know, these companies maintain research staffs?

A. Yes. Ciba, for instance, invented DDT.

Q. And, so far as you know, the gentlemen who comprise those research staffs are competent men in their field?

A. They get the best people they can get.

Q. I beg your pardon?

A. They get the best men they can get. They are continually robbing our laboratories of men like Charles Huggins.

Q. It is true, also, that these three large companies distribute great quantities of literature explaining to the physician the use of their products, do they not?

A. Very elaborate literature, beautifully illustrated.

(Testimony of Elmer Belt, M.D.)

Q. And isn't it a fact that the average doctor relies considerably on the statements that are contained in that literature, [401] as well as the contra-indications that are made?

A. Well, we have a phrase, cum grano salis, which we use there, I suppose.

Q. I have forgotten all the Latin I ever knew.

A. Until you get into legal verbiage, but that means with a grain of salt.

For instance, one company makes penicillin, and a brochure lies on my desk right now for that company's penicillin and its great efficacy in the treatment of syphilis. But it does not say anything at all about the other materials which are used in the treatment of syphilis and indeed used to much greater advantage in connection with this penicillin of theirs. Here is this beautiful brochure and it leaves out a very essential fact that one of their associates these days ever used an agent during the course of this treatment which will make better and more efficacious the use of their own product. That is the kind of thing one must be aware of, if he is listening to only one approach. Every practitioner realizes in reading the literature of a protagonist of one firm's substance, that he is reading biased literature and if he wishes to obtain real information, he can go to the original sources.

Actually, what the practitioner finds in reading this type of literature you are speaking of, advertising literature, is that the bibliography given at the end of [402] each of these articles is one of the

(Testimony of Elmer Belt, M.D.)

most valuable contributions of the person that he has before him, and he usually goes over to the library and has that material laid out for his use, so that he can control these observations by going back to their original sources, and it is just as you can read one paragraph and pervert the mind of your audience with that, you may find out that this company is using an isolated fact, which when read further is mitigated by other observations.

Q. Now, do you think that the average doctor has the time in which to run down that bibliography? And see whether or not it supports the text in the manufacturer's brochure?

A. Well, I am the director of the Los Angeles County Medical Library, the County Medical Association Library. It is astonishing the number of doctors that use that.

Q. You think that they do that? A. Yes.

Q. Do you think that doctors in reading this literature assume that the manufacturers have left out certain factual or important information on the subject in the brochure?

A. Oh, we know it so well.

Q. And the average doctor feels that way?

A. Oh, yes.

Q. The same would be true of contra-indications?

A. Oh, I suppose they would be very careful not to turn out a really poisonous product that a doctor would get into trouble with, if they could avoid it.

Q. Now, I am going to show you——

(Testimony of Elmer Belt, M.D.)

A. (Continuing): They might fail to list contra-indications properly, they might very well fail to do it. Again, there are little and big companies you know, and there are small companies which do not have the funds to carry out concepts like this, who are apt to give misinformation, that the large companies would not put out.

* * *

Q. (By Mr. Elson): Now, I have here a handbook, Schering Handbook, that I have shown to counsel, 1947 edition, and I refer to pages 11 and 12 dealing with Oreton, the trade name of their male sex hormone, and ask you, Doctor, to read that, please, and state whether or not you find anything there that contra-indicates that product in connection with an incipient cancer of the prostate or any kind of a cancer.

A. (The witness examines said handbook.)

Now, you wanted to know what, after I read this?

Q. Whether there is anything on those two pages that you read that contra-indicates the male sex hormone in [404] the case of an incipient cancer of the prostate or any other kind of cancer.

A. No. There is more than that, though, that I disagree with in this.

Q. Just a moment. The answer is you do not find anything like that? A. That is right.

* * *

Q. As a matter of fact, I am willing to introduce the handbook in evidence.

(Testimony of Elmer Belt, M.D.)

A. The answer to that question is no. What date is this?

Q. 1947.

A. That is already two years old.

Q. That is, I take it that it is 1947, copyright 1947. A. Yes.

The urogenic nature of testosterone propionate in elderly men was known before this thing was gotten out but, as I said before, here are two little passages and while you can't get [405] everything in here, they do say, "In elderly males, suffering with disorders in which unusual activity may be hazardous; a contra-indication."

Q. That is right.

A. Of course, that is a sort of come-on paragraph, because it makes the person reading it feel that surely this elderly male will have his sexual appetite, interest and ability to perform so stimulated that he will kill himself having sexual intercourse.

Q. And that is under the heading, though, of "Contra-indications," isn't it?

A. Yes, but it has that reverse implication which is very bad. It doesn't do any such thing. The French call that the sweet death. [406]

* * *

The Witness: All right. There is more, though, that is disastrous there, besides that. For instance, he refers all the way through to the male climacteric. I don't think there is any such thing.

Q. (By Mr. Elson): Pardon me?

(Testimony of Elmer Belt, M.D.)

A. He refers on those two pages, all the way through, to the male climacteric. I don't think the male has any climacteric. I think that most careful observers believe that, also, that there is no male climacteric.

Q. Well, isn't it true that that opinion that you have just expressed is one that is not universally shared by the profession?

A. Goodness. I don't know of any opinion that is universally shared by my profession or yours.

Q. Doctor, I agree with you. And it is also true, is it not, that there are many, many articles that have been written in medical journals on the subject of male climacteric?

A. In proportion to the number of loose thinkers that there are.

Q. Do you know Dr. August Werner?

A. Not wisely, but too well. [407]

Q. Of St. Louis? A. I know him.

Q. Do you consider him to be a loose thinker?

A. Yes, he is an example of the type of person who gets all mixed up in this problem and mixes up psychogenic problems, psychosomatic problems, with physiological ones and I think it is very bad.

Q. Do you know Dr. Hans Lisser of the University of California Medical School?

A. Yes. He was one of my teachers and, to a certain extent, he does the same thing.

Q. He is one of those loose thinkers?

A. To a certain extent.

Q. Do you know Dr. Escamillo?

(Testimony of Elmer Belt, M.D.)

A. I believe he is an associate of Hans Lisser.

Q. Do you consider him to be a loose thinker?

A. I think that some of the articles that they have put out on this subject are bad.

Q. Well, there is no use of taking the time to go into them all, but it is a fact that many, many articles have appeared in the Journal of Urology, the Urological and Cutaneous Review, and other similar medical journals in which various doctors have discussed the male climacteric, its symptoms and treatment, and so on?

A. The majority of the articles discuss it only to show [408] that it doesn't exist. There are a few individuals who believe that there is a male climacteric, but I think that the best thought is to the contrary. As a matter of fact, in Hollywood we say that a woman has a change of life but a man has a change of wife.

Q. Do you know Dr. Lester Hollender?

A. No, I don't.

Q. Dr. Harold R. Vogel? A. No.

Q. There is a publication, is there not, entitled The Archives of Dermatology and Syphilis?

A. Yes, sir.

Q. Was that considered to be an authoritative publication?

A. Yes. All of these are authoritative publications that you have mentioned, but they don't keep out articles because they present views which are contrary to the current accepted opinion.

Q. Well, without taking the time to go into all

(Testimony of Elmer Belt, M.D.)

of these things, it is true, now, isn't it, as a fact, that there have been many articles written by many doctors in these various publications in which they discuss the male climacteric, its symptoms and how it is to be handled and treated in connection with testosterone?

A. I suppose one could, on combing the literature for [409] that purpose, uncover numbers of them.

It is also true that in the two processes, the menopause in the female, that process is nothing like that which occurs in a man; the ovary atrophies, the menstrual cycle stops, the whole status of the woman changes.

Q. Doctor, I have just shown this little pamphlet to counsel, another publication of the Schering Corporation, a publication of the Medical Research Division, and entitled "A Rational Approach to the Treatment of the Male Climacteric," published in 1945, and ask you to read at the bottom of page 11 under the title "Genitourinary Effects," over to the end of that title on page 12.

Would you read it aloud? Then it will save me reading it later.

A. "Impotence, as a manifestation of the male climacteric is often amenable to androgen therapy and, as Lamar indicates, 'Sexual powers and libido can be restored in a moderate degree, bringing in many cases, peace and renewed marital happiness.'

"Urinary difficulties due to prostatism respond favorably to Oreton."

Prostatism is another field.

(Testimony of Elmer Belt, M.D.)

"Kearns observed 'a definite beneficial effect in the improvement in tone of the bladder as noted in cystometric measurements and in the detrusor action as evidenced by a better [410] empyting power and smaller amounts of residual urine. Subjective relief from frequency and dysuria has been noted consistently. The majority of the patients have also noted varying degrees of improvement in the urinary stream."

Q. Now, Doctor, do you agree or disagree with the statement that you have just read there concerning the subject of impotence?

A. I disagree with it.

Q. Do you know Dr. John R. Rand, of Portland, Oregon? A. Yes.

Q. He was one of the urologists that recently attended the American Urological Association meeting here in Los Angeles, in May of this year, was he not?

A. Yes, I believe he was here. I don't recall having seen him but I think he was here.

Q. Now, Dr. Rand was reported to have said, during or at the conclusion of that meeting, "We don't believe that men get cancer from taking male hormones or that women get other forms of cancer from taking female hormones."

Mr. Neukom: Wait a minute. Is that in a publication?

Mr. Elson: No.

Mr. Neukom: Is that in a publication?

Mr. Elson: No, no. He was reported to have said that. Let me go ahead.

(Testimony of Elmer Belt, M.D.)

Q. Did you hear Dr. Rand make such a statement? [411]

A. No, I did not hear him. That could be logical.

Q. For the purposes of the question only, let us assume that he did make it, would you agree or disagree with such a statement?

A. As far as that statement goes, I could agree with it. I don't believe they can get it that way either. I believe they already have it, that it would not grow and disturb them, and that the hormone causes it to grow and overflow out of bounds.

Q. That makes me think of something else. All men produce testosterone, do they not, men who have not been castrated? A. Yes.

* * *

Q. Can you say with any given individual the amount of [412] administered testosterone that would be necessary to accelerate the growth of a cancer of the prostate over and above that which he produces himself? [413]

A. Well, I am still balled up.

Q. Let's look at it this way——

A. I think what you are trying to say is, if the individual produces testosterone and you give him some more, will that light up the cancer. I think it will.

Q. How much more is necessary?

A. Nobody can say. It may be a very small amount or a very large amount. Dr. Huggins is taking a small island of growth which he had de-

(Testimony of Elmer Belt, M.D.)

tected of the prostate in the early stages of his work back in 1940, and probably that he could detect an increase in the size of that growth by giving testosterone and a decrease by giving stilbestrol, and he could alternate it and make it get larger or smaller. The same thing could be done using very small quantities of testosterone to increase the amount of acid phosphatase in the blood in an individual whose acid phosphatase level was a little high. If he gave just a small quantity of testosterone, the acid phosphatase would rise rapidly. If he gave stilbestrol, the acid phosphatase would drop and he could use that as an indicator of the spread of the growth.

Q. That would be after the cancer was a recognizable and a diagnosable cancer, wouldn't it?

A. Yes.

Q. I am talking about an incipient cancer. Say the man produced a certain amount of testosterone. Is that measurable? [414]

A. We only can measure it in amount as a discard.

Q. Do you consider that would be an accurate measure as to the amount that he produces?

A. No; it probably isn't but it is the only way we have of doing it.

Q. Then, let us say that that man takes a very small quantity of methyl testosterone. How are you able to say with certainty and not mere opinion that the growth of that cancer was accelerated

(Testimony of Elmer Belt, M.D.)

simply by what was given to him rather than by what he produced, or some other factor?

A. In those experiments that I have described, which Dr. Huggins performed, that was the only added factor, in the two cases which I described for you a few days ago. The added testosterone, in one case being methyl testosterone and in the other case being testosterone propionate, was the only unusual factor which could be called into account for a very unusual clinical phenomena. We are not magicians. We deal only with the materials we have at hand and the observations we can make. But, when you introduce one factor only which produces the very bizarre clinical phenomena, you are inclined to believe that that factor is the cause of the bizarre phenomena.

Q. Dr. Warren Nelson, who testified here the other day, talked about the subject of sterility and the effect of [415] testosterone on a person's sterility. He spoke about the damage to the testes that would occur under certain circumstances from its administration. He mentioned in his testimony, if counsel will pardon me for not going to the record for it—I couldn't put my finger right on it—that, in order to determine the amount of damage that had been done to the testes from the administration of testosterone, it would be necessary to take a biopsy and take a portion of the tissue of the testes and examine it microscopically. In your practice do you perfom biopsies on a man's testicles to deter-

(Testimony of Elmer Belt, M.D.)

mine whether or not testosterone is making him sterile?

A. No; we don't. We perform biopsies on testicles for other purposes but not for that.

Q. Do you know of any doctors who perform biopsies on a man's testicles for the purpose of determining whether or not the testosterone that he has been taking is making him sterile?

A. There is so much simpler method that I wouldn't think they would perform biopsies. One might wish to have that as the ultimate but, when we want to know whether the patient's sperm count is dropping, we have him masturbate and examine the specimen.

Mr. Neukom: Just a minute. I think you had better refer to the testimony of Dr. Nelson.

Mr. Elson: All right. Let's get the record. It is on [416] page 100. If I misquoted Dr. Nelson, I didn't mean to. This was his testimony after speaking about the administration of testosterone, page 99, line 2, "Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes? A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.

"Q. Is that the microscopic examination of a slide of a portion of the testes——

A. Yes, sir.

Q. ——Under a slide? A. Yes, sir.

(Testimony of Elmer Belt, M.D.)

Q. (By the Court): Just how do you get at that? How do you examine the testes under a slide?

A. A small piece of the testes is removed.

Q. (By the Court): By surgical operation?

A. By surgical operation, usually under a very simple local anesthetic. The tissue is properly fixed and sectioned and stained, the usual pathological procedure.

Q. (By the Court): How would that be called for except by just some experiment? That does not seem like a practical thing. Who would have that done?

A. It is being done very, very widely, now."

Q. Has that been your experience?

A. You are speaking now of a different thing than you spoke of there. When you brought up that subject, without reading the record, you spoke of the spermatogenic property [417] of the testicle——

Q. Wait a minute, Doctor. Let's not get into that. I wasn't talking about that at all. I was confining it simply to the broad question of sterility and the effect of testosterone upon a person, tending to make a man sterile.

A. Surely, but he is not talking about that there. What he is talking about is the testosterone-producing proclivity.

Q. Let me ask you this. Isn't it material to know whether a person is becoming sterile or not, by the use of testosterone—to know whether or not the testes are producing testosterone?

A. No. They are two different functions entirely of the testicle. The testicle produces spermatozoa

(Testimony of Elmer Belt, M. D.)

and the spermatozoa are the things which fertilize the female.

Q. But the testes in the interstitial cell also produce testosterone?

A. That is right. And testosterone is not an essential to the insemination of the female.

Q. Whether we do—— A. Now——

Q. Wait just a minute. Whether we do this for the purpose of determining whether the testosterone is making a man sterile or anything else, has it been your experience that the operation that Dr. Nelson refers to is done very, [418] very widely now?

A. For what he refers to, it is done widely.

Q. What is that?

A. That is to determine whether or not the endocrine part of the testicle is at fault.

Q. Do you mean experimentally or in actual practice?

A. In practice one can determine whether the testicular mechanism is below par in its activity or not by direct examination of the interstitial cells. It is not difficult to perform.

Q. If a man is not producing any sperm cells, he at least is infertile or becoming so?

A. If he is not producing any, he would be sterile.

Q. And, if the number of sperm cells that he is producing is not sufficient to reproduce, he has at least become infertile, hasn't he?

A. That is right.

Q. Is it your understanding of what Dr. Nelson

(Testimony of Elmer Belt, M. D.)

was talking about that that was an examination to determine whether or not the amount of the spermatozoa in the testes was sufficient or whether or not the man was becoming infertile?

A. No. Those are two different departments of thought. In one case it is a matter of the production of testosterone. In the other case it is a matter of the production of spermatozoa. [419] They are done by two wholly different things inside of the testicle. They are tested for differently to determine the number of spermatozoa and their activity and their form, and you simply have the patient bring you a post-coital specimen or have him ejaculate a specimen in the office by masturbation and examine it and that shows you this data. You are speaking of the department of fertility. A man can be totally infertile with azoospermia. An example of that is that of mumps of the testicle. Mumps orchitis will produce a complete azoospermia.

Q. Meaning what? A. No sperm.

Q. If he has no sperm, he can't produce, can he?

A. He can have sexual intercourse but he cannot reproduce.

Q. Let's get back to Dr. Nelson again. I am going back to page 98, line 5, "Q. (By Mr. Danielson): Can you make an opinion on the basis of your professional training, experience, education, your studies of the literature and the results of your conferences and discussions with other scientists and doctors, as to the effect of administered methyl testosterone on the testes?

"A. Yes. For instance, methyl testosterone has

(Testimony of Elmer Belt, M. D.)

quantitatively the same effect as testosterone, the effect on the testes is the same. [420]

"Q. What would that effect be?

"A. The inhibition of sperm cell production and the inhibition of the production of testosterone by the interstitial cells.

"Q. Would potency as such be a valid indication of whether the interstitial cells producing testosterone are or are not functioning under those conditions?

"A. No, because the administered testosterone would, of course, provide the necessary chemical agent for the induction of potency, in other words, the administered testosterone would take the place of the individual's own testosterone, which is no longer being produced in the same amount as before treatment.

"Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes?

"A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.

"Q. Is that the microscopic examination of a slide of a portion of the testes——" and then we went on.

Then, let's get down to page 99, line 21——

A. So far that is all very clear and logical.

Q. Just a minute. "Q. (By the Court): How

(Testimony of Elmer Belt, M. D.)

would that [421] be called for except by just some experiment? That does not seem like a practical thing. Who would have that done? A. It is being done very, very widely now. Q. It is? A. In cases of infertility or sterility or suspected disease or abnormal function of the testes. It is a widely recognized procedure at the present time."

A. Yes, sir.

Q. In actual practice?

A. In actual practice.

Q. Do you mean to say, Doctor, that, if a man has been taking testosterone and if the doctor suspects that maybe he is becoming sterile or infertile, that it is widely accepted practice for the doctor to take a biopsy of a portion of the man's testes and find that out?

A. No. You are reading a lot of things into Dr. Nelson's statement that he didn't make.

Mr. Danielson: I object to that as not being based on the facts quoted by Mr. Elson.

Mr. Elson: I don't think I am misquoting it.

A. No. You are just not understanding it, what Dr. Nelson says.

Q. Wait a minute——

A. Let me tell you——

Q. Wait a minute. Let me ask the questions first and then you tell me. Let's come right back to what he said on [422] page 100, where he said that it was widely done now. He said, "In cases of infertility or sterility or suspected disease or ab-

(Testimony of Elmer Belt, M. D.)

normal function of the testes. It is a widely recognized procedure at the present time."

A. Now, stop. He makes no reference to testosterone administered for any purpose then. He states that in infertility and in hypogonadism this is a widely recognized procedure and carried out.

Q. Let's go back to what he says. Let's go back to page 99, a question by Mr. Danielson as to whether, as a result, and so on, of his experience, he can testify or can state his opinion as to the effect of administered methyl testosterone. Then he goes on, on page 98 and on 99, which I will read, "Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes? A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone." What we are talking about is whether there had been any damage to the testosterone-producing portions of the testes by the administration of testosterone. "A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting [423] influences of the administered testosterone. Q. Is that the microscopic examination of a slide of a portion of the testes—— A. Yes, sir—— Q. Under a slide? A. Yes, sir. Q. (By the Court): Just how do you get at that? How do you examine the testes under a slide? A. A

(Testimony of Elmer Belt, M. D.)

small piece of the testes is removed. Q. (By the Court): By surgical operation? A. By surgical operation, usually under a very simple local anesthetic. The tissue is properly fixed and sectioned and stained, the usual pathological procedure. Q. (By the Court): How would that be called for except by just some experiment? That does not seem like a practical thing. Who would have that done? A. It is being done very, very widely now."

A. Right there he departs from the thought of testosterone.

Q. Just a moment. "Q. It is? A. In cases of infertility or of sterility or suspected disease or abnormal function of the testes. It is a widely recognized procedure at the present time."

A. Yes; that is right. For instance, if you walk down the street, you don't always walk down the street to your bank to get money. So you are separating the walking—— [424]

* * *

Q. (By Mr. Elson): Let's leave Dr. Nelson. As Mr. Danielson said, I think we can let the record speak for itself. In your direct testimony the other day, at page 249, line 16, the following questions and the following answers were given, "Q. Are there any subjective symptoms of this male hormone deficiency which a layman could recognize and accurately use to diagnose such condition?

"A. Oh, gosh, I wouldn't think a layman could know. He might confuse almost anything with loss of what he thought was his normal quantity of

(Testimony of Elmer Belt, M. D.)

hormones. If he just began to feel tired and run down or if his tennis arm was not satisfactory, or if he made too many strokes in his game of golf, he might decide that he was passing into the climacteric and therefore should take a few testosterone linguets.

"Q. Doctor, in your experience, has such been the case?

"A. Oh, yes. We are taking people off of this stuff all the time.

"Q. And what, as the result of your studies, has caused them to start using this preparation?

"A. They read in the newspapers they must. We have a gullible American public."

The Court: Which witness was it said that?

Mr. Elson: Dr. Belt.

Q. Do you know of Dr. Morris Fishbein?

A. Yes; I know him personally.

Q. And who is he, for the record?

A. He is a doctor of medicine who is licensed to practice in the State of Illinois and has his office in Chicago.

Q. Dr. Fishbein occupies some office with the American Medical Association, doesn't he?

A. Yes. I am not sure just what it is. I think he is secretary of the American Medical Association.

The Court: Executive secretary?

A. Executive secretary; yes.

Q. (By Mr. Elson): Dr. Fishbein, so far as you know, has a large part to do in guiding, at least up to recently, certain of the activities and policies of

(Testimony of Elmer Belt, M. D.)

the American Medical Association, or speaking for it? A. Yes; he has been doing that.

Q. And isn't it true, in your opinion, that the average well-informed layman knows who Dr. Fishbein is and associates him with the American Medical Association? A. I am afraid he does.

Q. Do you know whether or not Dr. Fishbien compiles certain medical information for the Cosmopolitan Magazine, under the portion which is called "New in Medicine"?

A. I believe he does write such a column. [426]

Q. I call your attention to the April, 1949, issue of the Cosmopolitan Magazine, under that heading, purporting to be compiled by Dr. Fishbein, and I call your attention to a short paragraph under "Testosterone and Fatigue." I will read it for the purpose of the record and then ask the question. "Experimental studies, by physiologic methods of frogs' muscles proved that animals injected with the male sex hormone, testosterone, had 10 per cent greater resistance to fatigue than ordinary animals. Administration of the male sex hormone before the study, increased the capacity to do more work by approximately 51 per cent. Furthermore, the male sex hormone reduced the rate of muscle fatigue during repeated periods of work." [427]

* * *

Q. Considering who Dr. Fishbein is, who he is considered to be by the average well-informed American, and an article such as that, would that statement, appearing in the Cosmopolitan Magazine,

(Testimony of Elmer Belt, M. D.)

would you consider a reader of that article to be gullible if he took that and inferred from it that testosterone might have the same effect upon him as it did upon the frog mentioned by Dr. Fishbein?

Mr. Danielson: Your Honor, I object to that as being incompetent, irrelevant and immaterial, improper cross-examination and argumentative.

The Court: I will sustain that.

A. It is a lot of fun anyway.

Mr. Elson: I was taking the statement of the witness about the gullibility of the American public.

Mr. Danielson: We will stipulate to that.

The Court: The court can take judicial notice of that. [428]

* * *

The Court: Before this passes out of my mind, I would like to ask the doctor a few questions. In your knowledge and observation of the cases you mentioned, where testosterone was administered for a certain kidney ailment and for a disorientation of certain patients and for sores that would not heal on the lower limbs, I am desirous to know if the administering of the drug in those cases, over a considerable period of time and a considerable quantity of the drug—if there was any observation of record as to whether that had in any manner promoted any cancerous or stimulated any cancerous condition in the prostate of the male concerned or in the breast of the female concerned.

A. No, we have never seen it do that, but we have always examined these patients carefully first

(Testimony of Elmer Belt, M. D.)

to be sure [429] that we haven't any evidence of the existence of malignant cells or cells that are suspicious of being malignant, before we begin that type of therapy, and in that I am speaking of the group of elderly men you had referred to. But in the other case, these young people are usually below the age of 45 and there is less danger of causing that kind of trouble in persons under 45 years of age. In fact, I believe there have been no observations that tend to show that cancer would be enhanced in individuals of that age because they don't have the little groups of cells that initiate the growth.

The Court: Counsel may proceed.

Mr. Elson: I don't think I will take very much longer.

Q. By the way, do you know who Dr. Elmer L. Sevringhaus is? A. No.

Q. To refresh your mind, isn't he the director of medical research for the Roche-Organon Company?

A. My goodness, I wouldn't know that.

Q. Do you know of a book called The Modern Home Medical Adviser?

A. Is that by Dr. Morris Fishbein?

Q. Yes; edited by him.

A. I have never seen it.

Q. There is a chapter in this book entitled "Endocrinology" by Elmer L. Sevringhaus—his identity is not [430] material—commencing on page 550, the subject being "The Testes or Male Sex Glands," which are discussed. I don't think that it is necessary to read the whole thing in the record. The

(Testimony of Elmer Belt, M. D.)

portion that I have in mind is only one sentence, the last sentence in the paragraph, at the top of page 551. It reads, "In summary, it may be said that testosterone is the hormone which is required to stimulate development from boyhood to manhood, and to maintain typically manly qualities thereafter." [431]

In your opinion, would a layman be considered gullible who read that and believed that testosterone or the male sex hormone product would maintain typically manly qualities after he had reached manhood? A. No; he wouldn't.

Q. If I told you, Doctor, and I will shortcut this and I think counsel will not object to it—if I told you that in this book, which is obviously for consumption of the layman, there is no reference to testosterone, possibly, probably or otherwise encouraging or affecting or accelerating the growth of a cancer of the prostate, don't you think that the average person reading that would, therefore, eliminate or it would never enter his mind that testosterone would have anything to do with such acceleration?

A. If that was his only source of knowledge and he depended upon that wholly for everything he knew, he probably would be allowed to come to that conclusion.

Q. You haven't seen this book, have you?

A. No; I haven't seen it before.

Mr. Elson: I might say that the book is edited by Morris Fishbein, M. D., your Honor, the gentle-

(Testimony of Elmer Belt, M. D.)

man whom Dr. Belt has described, and on the title page it says, "Modern Home Medical Adviser for Health and How to Preserve It, Edited by Morris Fishbein, M. D."

A. Home doctor books are as old as the world.

The Court: I should like to ask you, Dr. Belt, if that book or any publication, which seems to have the editorship of a man of the standing of Dr. Fishbein, if it extols the virtues of a drug for the purpose mentioned and it is silent as to any of its dangers from the effects of the use of the drug, would you regard that as a dangerous publication?

A. In that way it is, of course. I have never seen that book but I am sure you will find statements throughout which repeat often that a layman should not self-administer drugs. I am certain that Dr. Fishbein would not produce a book of that sort without giving that warning.

* * *

Mr. Elson: I only have one or two other questions.

Q. Doctor, do you think that a man who is in middle age or life and who complains of these various symptoms, such as flushes, sweats and so on, as was enumerated, without repeating them, that the question of his sterility or fertility [433] is important at his age compared to his desire to be relieved of those symptoms?

A. So many things crowd into my mind as a result of that question that I will say it is difficult

(Testimony of Elmer Belt, M. D.)

to separate them into an understandable flow of thought, but I will try to. Whatever a man is beset with at the moment is an important thing to him. If he has hot flushes and feels tired and weary and all that, it is a very important thing to him at that moment. But in the long view, it may be of much greater importance to that man to maintain his fertility.

Q. Why?

A. Suppose a man is 40 years of age and he has three children and he has a wife, and the three children and the wife go merrily down the road in the new automobile that he has bought for them, and they are all killed. The day before their death he thought he would never have another child. But a few months later, he marries again and marries a young woman and then the matter of propagation is of importance.

Q. Don't you think that is a far-fetched analogy?

A. Not when there were over 600 people killed over this Fourth.

Q. Well, take a man 40 years old. Is that a far-fetched analogy?

A. No. You are wrong there. You should practice medicine and see the number of people who change their wives at 45. [434]

Q. (By Mr. Elson): Isn't it true that there are a lot of men who have vasectomies performed?

A. Well, they try to have in males. We discourage it pretty much.

(Testimony of Elmer Belt, M. D.)

Q. Well, vasectomy, explain to the court what it is.

A. Vasectomy is a method of severing the duct between the testicle and the seminal vesicle in order to produce sterility through blocking the flow of sperm into the seminal vesicles and preventing the female partner from being inseminated and fertilized.

The Court: That can be restored, though, by another operation, can it not?

The Witness: Your Honor, the possibility of restoring it is remote. I have tried it in about 15 cases. I have only seen one patient who had babies afterward. We have seen spermatozoa appear in the ejaculation afterward, but these patients apparently don't fertilize their partners because the spermatozoa seem to appear in too small numbers, and that is the general experience with that operation. After the vas has been occluded for a long period of time, the sperm count in the restored ejaculated sperms seems invariably to be low.

Q. (By Mr. Elson): Do you feel that before testosterone should be prescribed to a person, that the doctor ought to warn that it may cause him to be sterile? [435]

A. A young person I think should be, yes.

Mr. Elson: I think that is all.

(Testimony of Elmer Belt, M. D.)

Redirect Examination

By Mr. Danielson:

Q. What do you mean by azoospermia? Is that the same as sterility?

A. Azoospermia means that there are no spermatozoa. "A" is the Greek derivative.

Q. Azoospermia would produce sterility, then?

A. Yes.

Q. Do you perform the acid alkaline phosphatase test in your urology group? A. Yes.

Q. That is a procedure which you follow from time to time, is that correct? A. Yes.

Q. Doctor, a good deal was asked as to what would a general practitioner do under the circumstances comparable to the so-called male menopause. A. Yes.

Q. Now, you mentioned the precautionary examinations which were given. Assume for a moment, Doctor, that the patient told you that he was referred by another doctor who gave him such drugs from time to time, would that change the procedure at all?

A. Well, if a patient comes to me referred by another [436] physician, I always allow the other physician the benefit of whatever doubt that might exist in my mind and my tendency is to go on with the original treatment he has established until I can communicate with him and discuss the problem with him. It is possible that the patient may not tell me things that he has communicated to his other physi-

(Testimony of Elmer Belt, M. D.)

cian. It is possible that I may not see things in that patient that the other physician saw. So, in the first place, a generously disposed human being would not say right away, "Oh, your doctor is doing the wrong thing. By goodness, this is the trouble." But you would conform to the treatment until you had an opportunity for discussion and coming to a common understanding of that.

Q. That is what I had in mind. Now, would counsel object to my reading a small paragraph from one of these articles?

Mr. Elson: No.

Mr. Danielson: This is a reprint from the Northwest Medicine, of Seattle, Volume 46, No. 12, page 949, December, 1947. The article is entitled "Present Status of Male Hormone Therapy." From the second page I quote:

"Caution: Male hormone is contra-indicated, if there be any suspicion of cancer of the prostate, and had better be avoided in cases of arteiosclerosis, hypertension and cardiac disease." [437]

Q. Doctor, as to that one particular phrase, do you have any dispute? A. No.

Mr. Danielson: No further questions.

Recross-Examination

By Mr. Elson:

Q. In other words, Doctor, as to that particular

A. Oh, well, you must understand that we all have our hobbies and a hobby is something that

(Testimony of Elmer Belt, M. D.)

makes a man bend over backward in one direction. It is a slant——

Mr. Elson: Well, I think I was being a little facetious. I have no further questions. [438]

* * *

Mr. Neukom: It will be stipulated, will it not, Mr. Elson, that a document similar to Government's Exhibit 14-A, the pamphlet, was passed out and was available to whosoever might be interested?

Mr. Elson: That is correct.

Mr. Neukom: In addition to that, at the time in question [441] and prior to the dates in question, there was run in local newspapers of general circulation various advertisements advertising these hormone products by the defendant here. Is that correct?

Mr. Elson: Correct.

Mr. Neukom: Without offering those, your Honor, we will merely enter into a stipulation that from time to time the local newspapers offered for sale male and female hormones, without the necessity of a prescription. I mean the local newspapers printed the advertisements.

Mr. Elson: That is correct. [442]

* * *

Mr. Danielson: If your Honor please, the government is prepared at this time to stipulate that the transactions reflected in the first nine counts, counts 1 through 9, inclusive, of the information, involve sales and shipments to government agents,

agents who communicated with the defendant and made the purchases which were subsequently made with the drugs being sold to these government agents and shipped to the government agents. This was done in the regular course of business, however.

Mr. Elson: That is right.

The Court: The allegations from what?

Mr. Danielson: 1 through 9.

Mr. Elson: Counts 1 to 9, inclusive.

Mr. Danielson: That is correct.

The Court: 1 through 9.

Mr. Danielson: These transactions were between the defendant and government agents, in the regular course of business.

* * *

The Court: Now, the government rests?

Mr. Danielson: The government rests, your Honor.

Mr. Elson: When I did it before, maybe it was premature, [445] but at least for the record I make a motion for a judgment of acquittal in the case of United States of America vs. El-O-Pathic Pharmacy, Inc., et al., No. 20596 Criminal, and I also make a motion for a judgment of acquittal in the case of United States of America vs. Allen H. Parkinson, No. 20642 Criminal.

The Court: I will hear you on the motions.

Mr. Elson: Well, your Honor, I will be very, very frank. I think that Mr. Sturzenacker concurs with me that I am making that motion for the purpose of protecting my record and I did not intend

to and, frankly, am not prepared at the present time to argue extensively any such motion.

The Court: The motion is denied.

The Clerk: Your Honor, is that in both cases?

The Court: In both cases, yes. They were made at the same time. [446]

* * *

The Court: In the El-O-Pathic case let the ruling be considered in accordance with that, then.

Mr. Elson: And then I withdraw my motion as to the Parkinson case.

The Court: And the ruling of the court in the Parkinson case is withdrawn?

The Court: Yes, because there is nothing before the court—no motion before the court. [448]

* * *

MARTIN A. CLEMENS

one of the defendants herein, called as a witness on behalf of the defendants, being first duly sworn, testified as follows:

Direct Examination

The Clerk: Your full name? [455]

The Witness: Martin A. Clemens.

Q. (By Mr. Elson): Mr. Clemens, what is your connection with the El-O-Pathic Pharmacy, Inc., a corporation?

A. I own the stock in the company.

Q. And you are the manager and director of the corporation? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. Do you also operate the M. A. Clemens Pharmacy? A. I do.

Q. Now, are you a pharmacist?

A. Yes, sir.

Q. Admitted to practice pharmacy in this state?

A. Yes, sir.

Q. How long have you been? A. 1927.

Q. Now, you sell, do you not, testosterone?

A. I do.

Q. And, in other words, the other products that are mentioned in the information? A. I do.

Q. Now, at least in the fall of 1947, from whom were you buying those products?

A. From the Roche-Organon Company, Ciba Pharmaceutical Supply, from the Schering Corporation.

Q. In connection with the products that you purchased [456] from them, did you also receive literature from those companies?

A. Yes, sir, we did.

Q. And you have seen the literature, some of it that has been introduced or used in the course of this trial so far? A. I have.

Q. Was that similar to the literature that you received at least from those companies?

A. It was.

Q. Now, in connection with this pamphlet, "Male and Female Sex Hormones," an exhibit in this case, what was the source of the information contained in that pamphlet?

(Testimony of Martin A. Clemens.)

A. It was paragraphs taken from the manufacturers' pamphlets.

Q. One manufacturer or several?

A. All of them.

Q. How long have you been selling testosterone?

A. Since 1943.

Q. Has anyone, at any time, made any complaint concerning the alleged damage or injury from the use of the product to you?

A. They have not.

Q. Are you able to tell us approximately how much testosterone you have sold since 1943? [457]

A. In boxes, or in amount of pills?

Q. In boxes?

A. Approximately 127,000 boxes. [458]

The Court: Were they all the same size?

A. They were different sizes.

The Court: It doesn't seem to mean much, then, unless there is an average as to the quantity. 127,000 boxes varying in size doesn't convey much meaning to the court.

Mr. Elson: Let's try and do it this way.

Q. Approximately how many tablets have you sold since 1943?

A. Between four and five million tablets.

Q. And how are those tablets sold; in what sized boxes?

A. Well, originally they were sold in boxes of 15, 30s and 100s and later on the manufacturer changed them to 30s and 100s and 500s.

Q. Can you give us an estimate of about the

(Testimony of Martin A. Clemens.)

percentage of business that comprised the 15 tablets to a box?

A. That was a small percentage. I don't remember the exact amount.

Q. I show you here a paper, on the letterhead of the El-O-Pathic Pharmacy, and ask you if you recognize the handwriting.

A. That is my handwriting.

Q. How long ago did you prepare that?

A. In the past 10 days.

Q. After having looked at that, is your memory refreshed as to the approximate percentage of your business [459] that comprised sales of 15 to a box?

A. It is.

Q. How many? A. 20 per cent.

Q. And approximately what percentage of your business comprised the boxes of 30 tablets to a box?

A. 30 to 50 tablets; 70 per cent.

Q. And what percentage of your business comprised the sale of tablets of a hundred to a box?

A. About 10 per cent.

The Court: You didn't mention the 500.

Q. (By Mr. Elson): Did you say 500?

A. We very rarely sell 500s. It is usually used for dispensing in smaller bottles.

Q. In other words, it is a negligible quantity?

A. That is right.

Mr. Elson: Does that answer your Honor?

Q. Did you carry Products Liability Insurance?

A. We did.

Q. That is, do you carry it now?

(Testimony of Martin A. Clemens.)

A. We do.

Q. How long have you carried it?

A. Approximately five years.

Q. With one company or several?

A. The past three years it has been with one company. [460]

Q. And who is that?

A. The United States Fidelity and Guaranty Company of Baltimore, Maryland.

Q. Do you remember who you were insured with for that purpose prior to that time?

A. No; I don't.

Q. What is the amount of insurance that you carry?

Mr. Neukom: I will object, your Honor. It is not material.

Mr. Elson: I will withdraw it.

Q. Now, Mr. Clemens, in Counts 5, 7 and 9, it is alleged that you sent to the persons referred to in those counts, on the dates mentioned in those counts, testosterone. It is not alleged that there was any accompanying literature with those shipments, such as is referred to in the other counts, and by that I mean the pamphlet "Male and Female Sex Hormone." Do you get that? A. No; I don't.

Q. In Counts 5, 7 and 9 of the information, it is alleged that you shipped testosterone or mailed it to the individuals referred to in those separate counts and that you mailed that to them on the dates that are referred to in each of those counts. It is not alleged, however, that with those shipments

(Testimony of Martin A. Clemens.)

went the pamphlet here, "Male and Female Sex Hormone"; in other words, that it didn't accompany it at all. [461] Do you get me now?

A. Yes, sir.

Q. Do you remember whether or not with those particular shipments referred to in those counts—do you have any independent recollection of having shipped one of these pamphlets here and—well, go ahead and answer.

A. One or two pamphlets went out with every shipment.

Q. Was that your usual and customary practice?

A. Yes, sir.

Q. Was it infrequent or invariable?

A. Always.

The Court: As a part of the shipment or under separate cover?

A. A pamphlet went out with every shipment.

The Court: That is, right along with the package? A. Yes, sir.

The Court: In the same package?

A. Yes, sir.

Q. (By Mr. Elson): In Count 10 the allegation is made that you shipped a box with the labeling "Female" on it. Do you remember that?

A. Yes, sir.

Q. I will show you a photostatic copy of the governments exhibit here and it is alleged that you sent this alpha estradiol in that package, with that scratched out and [462] with the word "Female"

(Testimony of Martin A. Clemens.)

written on there. Do you remember that particular transaction? A. I don't.

Q. What was your practice with regard to sending out estradiol or female hormones, in so far as any literature was concerned on the female hormones?

A. We used the manufacturer's literature to accompany the product. If it was Schering, we would use Schering's literature, or, if it was Roche-Organon, we would use Roche-Organon literature.

Q. On the female you sent manufacturer's literature? A. That is correct.

Q. I show you here a brochure of Roche-Organon, having to do with oral estrogen therapy, and ask you if you have seen that before.

A. I have.

Q. Is that the manufacturer's literature to which you referred? A. Yes, sir; it is.

Mr. Elson: May I offer this in evidence, please?

Q. Was it infrequent or your invariable practice to send such brochures with such product?

A. The brochures went out with every order.

Mr. Elson: We will offer this as the defendants' next exhibit. [463]

The Clerk: That will be Defendants' Exhibit C in evidence.

(The document referred to was marked Defendants' Exhibit C and received in evidence.)

Q. (By Mr. Elson): On some of these shipments did you take out of the original package in

(Testimony of Martin A. Clemens.)

which it came cellophane packages containing tablets of testosterone? A. We did.

Q. After having taken those out, did you send those to persons who ordered them?

A. We did.

Q. These tablets came in what form?

A. They came in boxes of a hundred tablets, 20 strips to the box.

Q. By "strips" do you mean they were in cellophane strips? A. That is correct.

Q. Similar in appearance to this one I am holding in my hand now? A. Exactly.

Q. And, when a person ordered say five tablets or ten tablets, or we will say less than the number contained in the original package, how did you fill the order?

A. We reboxed them and put a circular in with them.

Q. What do you mean by reboxed them? [464]

A. We put them in a separate mailing box.

Q. Do you mean the strips? A. Yes.

Q. And mailed them with the circular?

A. With the circular.

The Court: Was it this circular or was it another one?

A. It was the male hormone circular.

Q. (By Mr. Elson): I show you here a circular or brochure—counsel has stated that they don't have any objection to my speaking to the witness a minute.

(Testimony of Martin A. Clemens.)

(Inaudible conversation between Mr. Elson and the witness.)

Q. Now, in Count 5 it is alleged that you removed five tablets from an original package that you received from Roche-Organon and shipped that or you mailed it to somebody in some other State. I can't remember now who it is. Do you recall that?

A. That is right.

Q. I show you here a brochure entitled "Oral Androgenic Therapy, Roche-Organon." Have you seen those before? A. Yes, sir; I have.

Q. Now, what was your practice with reference to products received from Roche-Organon in which you removed say five or ten tablets and sent those by mail?

A. We sent a circular along with it. [465]

Q. Such as this one here?

A. Yes, sir.

Mr. Elson: I offer this as the defendant's next exhibit.

The Clerk: That will be Defendants' Exhibit D in evidence.

(The document referred to was marked Defendants' Exhibit D and received in evidence.)

Q. (By Mr. Elson): Did you receive similar brochures from the other two companies, Ciba and Schering? A. We did.

Q. That described the use of the product and so on? A. Yes, sir.

(Testimony of Martin A. Clemens.)

Q. Was your practice the same in connection with taking out five or ten tablets, of Schering or Ciba, which you mailed to somebody in another State? A. It was.

Q. You mailed the brochure that was Schering's—if it was Schering's tablets, you mailed their brochure along with them?

A. Yes, sir; that is correct.

Q. And the same would be true of Ciba's?

A. Yes, sir.

The Court: You mailed a copy of this circular or one that you had printed yourself, which?

A. We mailed that circular. [466]

The Court: This one?

A. Yes, sir.

Q. (By Mr. Elson): You received considerable quantities of such circulars from the manufacturers? A. We did.

Q. When I say considerable quantities, about how much did you receive from them?

A. As many as we needed.

Q. Would it go into the hundreds or thousands?

A. Thousands.

Q. In Count 2 the charge is that you shipped certain Menformon Dosules, a product of Roche-Organon Company, to a person in Phoenix, Arizona. Those dosules are an ointment, are they not?

A. That is correct.

Q. For the purpose of being rubbed on a woman's breast? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. You purchased those from Roche-Organon?

A. We did, sir.

Q. In Count 3 it is alleged that you sent those dosules to John R. Winch in Phoenix, Arizona. Did you send those in the original package in which they were received by you from the manufacturer?

A. Yes, sir.

Q. In connection with that product, did you—or was [467] there any accompanying brochure or literature that went with it?

A. Yes, sir; there was.

Q. I show you here defendants' exhibit I guess it is. Is that the product that went with it?

A. Yes, sir; it was.

Q. Or I mean brochure.

A. Yes, sir; it was.

Q. And that was the brochure that you received from Roche-Organon? A. Yes, sir.

Q. Now, I show you here two invoices, one dated December 3, 1947, and the other one dated September 18, 1947. Keeping in mind the date of shipment in Count 3, December 28, 1947, was the product that you shipped under Count 3, on December 28, included within the merchandise covered by either of those invoices? A. Yes, sir; it was.

Q. Which one would it be, if you know?

A. The one that is dated December 3, 1947.

Mr. Elson: I offer that invoice into evidence.

* * *

The Clerk: Defendants' Exhibit E in evidence.

(Testimony of Martin A. Clemens.)

(The document referred to was received in evidence and marked Defendants' Exhibit E.)

The Court: May I ask the witness a question now?

Q. In this Male Sex Hormone Androgenic Therapy, there is a statement to the effect that if X-ray examination discloses evidence of increased bone age, that the use of the drug should be discontinued. What does bone age mean?

A. Oh, that is a medical term, your Honor.

Q. (By Mr. Elson): Have you ever yourself used testosterone? A. I have. [474]

Q. For how long?

A. The past two years.

Q. And in what size doses?

A. A hundred milligrams weekly by injection, and from 25 to 50 milligrams daily, to supplement it.

Q. Injections by a doctor? A. Yes, sir.

Q. After having taken this product, describe how you felt.

A. Well, it gave me a lift, it gave me a sense of well-being, it kept me from being loggy.

Q. In other words, you felt better?

A. Felt better.

Q. So far as you know, you suffered no ill effects? A. None whatsoever.

The Court: How long did you say you took it?

A. The past two years.

The Court: Regularly all this time?

(Testimony of Martin A. Clemens.)

A. Yes, sir.

The Court: Two years. You started out with that dose and continued it right along?

A. I started out with 25 milligram doses and then, when the manufacturer increased the strength of the product to the same—well, they used to manufacture 25 cc's to the injection and now they manufacture 50 to each injection and I [475] increased the doses at the time.

The Court: You doubled it?

A. Yes, sir, your Honor.

The Court: And took it daily, hypodermically?

A. No. Once a week. Daily, orally, by sublingual.

* * *

Q. (By Mr. Elson): Mr. Clemens, have you gone to other drug stores in the State of California and purchased testosterone? A. I have.

Q. In what form? A. Tablets.

Q. Linguets or tablets?

A. Tablets and linguet form.

Q. Where have you done that?

A. Up and down the state.

Q. Well, explain what you mean, please?

A. On a trip to San Francisco, I stopped at every town I got a chance to and if they had four drug stores I would go into two of them and make a buy. I had no difficulty.

Q. You purchased it over the counter?

A. Yes. [476]

Q. Have you made any such purchases in the city of Los Angeles? A. I have.

(Testimony of Martin A. Clemens.)

Q. Recently? A. Yes, sir.

Q. Where?

A. Oh, practically any store.

Q. Well, let us put it this way: At many drug stores or only a few? A. Many.

Q. By many what do you mean?

A. Well, I would say nine out of ten.

Mr. Elson: Cross-examine.

Cross-Examination

By Mr. Danielson:

Q. How old are you, Mr. Clemens?

A. 42.

Q. Have you ever been convicted of a felony, Mr. Clemens? A. No, sir.

Q. Never? A. No, sir.

Q. Now, Mr. Clemens, you have mentioned that in all of your sales of the hormones you transmitted various circulars or circulars at least with these shipments, is that correct? [477]

A. That is correct.

Q. And that was true of this little pamphlet, "Male and Female Sex Hormones," the little pamphlet of your own, is that not correct?

The Court: What was the answer?

Q. (By Mr. Danielson) (Continuing): I am referring specifically, Mr. Clemens, to what appears as Government's Exhibit 2-A and comparable circulars.

The Witness: Now, what is the question, sir?

(Testimony of Martin A. Clemens.)

Q. (By Mr. Danielson): You transmitted these circulars with your shipments, likewise, is that correct? A. Yes, sir.

Q. And that is true of all of these shipments and transactions which are reflected in this information, is that not correct? A. That is correct.

Q. Now, Mr. Clemens, I direct your attention to a transaction of November 1, 1947, which is the subject of the first count of this information alleging the shipment of a package of male hormones to John R. Winch of Phoenix, Arizona. Do you remember that particular transaction?

A. Yes, sir.

Q. Do you remember what was the labeling you transmitted with that particular shipment?

A. What was on the label? [478]

Q. What circulars or pamphlets, literature, did you transmit with that shipment?

A. If it was a male hormone, we sent them the literature from the male hormone leaflet.

Q. You sent them this pamphlet "Male and Female Sex Hormones," is that not correct?

A. Yes, sir.

Q. And did you send any other literature?

A. Manufacturers' literature.

Q. You are sure of that? A. Yes, sir.

Q. You remember that particular incident, is that correct, this particular transaction?

A. I do not remember that particular transaction, but one of them went into every package. I inspect every order that goes out.

(Testimony of Martin A. Clemens.)

Q. But you do not remember that particular transaction, do you? A. No, sir.

Q. All you know is that there was such a shipment? A. That is right.

Q. Now, I invite your attention to what is known as count 2 of this information. It involves a sale, a shipment on or about October 30, 1947, to John R. Winch, Phoenix, Arizona, again of a package of tablets containing 25 milligrams [479] of testosterone each. Do you remember that particular shipment?

A. No, I don't remember that particular shipment.

Q. Do you know what labeling went out with it, what circulars and literature?

A. If it was a male hormone, a male hormone circular went with it.

Q. Both your own pamphlet, the "Male and Female and Sex Hormones," and you say some manufacturers' literature went with it?

A. That is right.

Q. Now, Mr. Clemens, I invite your attention to what is count 3 of this information, which is based on a shipment of Menformon Dosules to John R. Winch of Phoenix, Arizona. Do you remember that particular shipment? A. I do.

Q. You do? A. Yes, sir.

Q. And what literature accompanied that shipment?

A. Manufacturers' literature with the description of the bust development.

(Testimony of Martin A. Clemens.)

Q. And what else? A. And our pamphlet.

Q. And now you are referring to this "Male and Female Sex Hormones" pamphlet? [480]

A. That is correct.

Q. Now, Mr. Clemens, as to count 4 of this information which is based on a transaction on or about November 18, 1947, and a shipment to Robert C. Brandenburg—rather, a sale to Robert C. Brandenburg, do you remember that particular transaction? A. No, sir.

Q. Do you know what literature accompanied that transfer of hormones, 25 milligrams testosterone?

A. Testosterone—manufacturers of testosterone literature and our own.

Q. You are certain of that? A. Yes.

Q. Now then on count 5 of the information we have a transaction, five tablets of 25 milligrams testosterone sold to Robert C. Brandenburg on or about November 18, 1947. Do you remember that particular transaction? A. No, sir.

Q. Do you know what literature would have accompanied it?

A. The literature of the manufacturer.

Q. Plus your own? A. Plus our own.

Q. ——pamphlet, the "Male and Female Sex Hormones"? A. That is correct. [481]

Q. And to count 6 of the information charging that on or about October 27, 1947, a quantity of five tablets of 25 milligrams testosterone was sold to one

(Testimony of Martin A. Clemens.)

Allen T. Spiher, Jr. Do you remember that transaction? A. Would you repeat that, please?

Q. Allen T. Spiher, Jr., a sale of 5 tablets containing 25 milligrams of testosterone each.

A. Was that a shipment?

Q. It was on or about October 27, 1947. These tablets were placed into an envelope and sold and disposed of to Allen T. Spiher on the surrender of nothing but money, in payment therefor. Do you remember that transaction?

A. That was an over-the-counter sale?

Q. Apparently it was. A. Yes, sir.

Q. Do you remember what literature accompanied that sale? A. No, I don't.

Q. You don't remember on that. Would that transaction have been different from the other transactions we have just covered?

A. It would.

Q. Why would that be?

A. I knew he was a federal drug inspector.

Q. And you don't know what literature it accompanied, [482] however? A. No, sir.

Q. I take it that you know Mr. Spiher, is that correct? A. That is correct.

Q. Now, in count 7 of the information, it alleges specifically that on or about October 27, 1947, a sale again of five tablets of 25 milligrams testosterone, again to Allen T. Spiher, Jr. Do you remember that transaction? A. I do.

Q. Do you remember what literature accompanied it? A. No, sir.

(Testimony of Martin A. Clemens.)

Q. And in count 8?

A. Was that an over-the-counter sale?

Q. Apparently it was.

A. Or was that a shipment? Then, the answer is the same.

Q. And in count 8 of the information, on or about November 20, 1947, a sale again of five tablets of 25 milligrams testosterone to one Allen T. Spiher, do you remember that transaction?

A. I do.

Q. And do you remember what literature accompanied it? A. I do not.

Q. And in count 9 of this information, a transaction on or about November 20, 1947, a sale of five tablets containing [483] 25 milligrams each of testosterone to one Allen T. Spiher. This apparently is over-the-counter likewise. Do you remember that transaction? A. I do.

Q. And do you remember what literature accompanied it? A. I do not.

Q. Now, directing your attention again, Mr. Clemens, to the transaction involving the sale of Menformon Dosules, I believe you have testified that the information contained in your little blue pamphlet, your Male and Female Sex Hormones pamphlet, was lifted from the literature of some manufacturer, is that correct? A. That is correct.

Q. Is the literature in your own pamphlet substantially that which appeared in this manufacturer's pamphlet? A. That is correct, sir.

Q. Without any material changes in it?

(Testimony of Martin A. Clemens.)

A. That is right.

Q. How did you copy it from there? You yourself decided what portions to reincorporate in your own, is that not right?

A. It is just cut out of the original pamphlet and pasted onto a sheet.

Q. You read it before you did that, did you not?

A. Yes, sir. [484]

Q. Then, you noticed the full text of the manufacturer's pamphlet, including the citation of some authority? Is that not correct?

A. I do not have the pamphlet here in front of me.

Mr. Danielson: Do you have Defendant's Exhibit A here?

The Clerk: Yes.

Q. (By Mr. Danielson): Mr. Clemens, I will invite your attention to Defendants' Exhibit A which purports to be a little brochure relative to Menformon Dosules, particularly to the bottom of page 2. Now, I ask you, Mr. Clemens, is that the portion that you incorporated in your little pamphlet of "Male and Female Sex Hormones"?

A. I do not remember. I do not have a pamphlet here.

Q. It is right there.

(Mr. Danielson indicates exhibit to the witness.)

A. This paragraph was taken from this pamphlet right here (indicating).

(Testimony of Martin A. Clemens.)

Q. When you say "this paragraph," identify what document you are talking about.

A. The last paragraph on the circular of our own.

Q. That is on the bottom of what would be page 4, the back sheet, am I not correct?

A. That is correct, and it was taken from——

Q. Defendants' Exhibit A?

A. Defendants' Exhibit A. [485]

Q. (By the Court): It has a subheading, "Results from male hormones," is that right?

Mr. Danielson: No, your Honor. On the bottom of page 4 of the little blue pamphlet, the reverse page, the back page, under the heading "Breast Development." That was lifted from the second paragraph on the second page of Defendants' Exhibit A, is that correct? A. That is correct.

* * *

Q. (By Mr. Danielson): Now, Mr. Clemens, I should like to point out to you that in the manufacturer's brochure, in referring to these hormones, does he not cite various authority such as C. M. McBride, J.A.M.A. 1932, 112:1045, that is cited in Defendants' Exhibit A, is that not correct, the manufacturers' literature? A. That is correct.

Q. And it is not cited, however, in your personal literature, is it? A. No, sir.

Q. But, nevertheless, in reading it—you edited that [486] out, you eliminated that yourself, is that not correct? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. Now, you testified, did you not, that these manufacturers would supply you with all the literature you wanted, that is, any quantity of literature that you would want? A. That is correct.

Q. Up to several hundred thousand copies, if need be, is that correct? A. That is correct.

Q. That is likewise true of Roche-Organon, is that not correct? A. That is correct. [487]

* * *

Q. (By Mr. Danielson): Why did you find it desirable, Mr. Clemens to lift out this portion from the manufacturer's brochure and put it in your own?

A. You mean why I decided to omit that one sentence?

Q. No. Why did you find it necessary to reprint the manufacturers' brochures when they would supply you with all the copies you wanted?

A. They quit supplying them.

Q. I thought you said they would supply you with all the copies you wanted.

A. They did, for a while.

Q. As a matter of fact, wasn't it more convenient to omit those portions which referred to the medical literature?

A. No. That wasn't correct.

Q. Now, as to all this literature which accompanied these transactions, Mr. Clemens, you remember that in the instances other than those involving Mr. Spiher, do you remember, are you sure that the other literature went along with those, the manu-

(Testimony of Martin A. Clemens.)

facturers' literature accompanied those transactions? A. Yes, sir.

Q. As a matter of fact, isn't it true that it is a rather convenient afterthought, two years afterwards, to remember that some other literature accompanied them?

A. No, sir. We always had a policy to put one or more circulars in every package, and they were always checked. [488]

Q. Now, you have testified that you sold around four to five million tablets of methyl testosterone since you have been in this particular business, is that not correct? A. Yes, sir. [489]

* * *

Q. (By Mr. Danielson): In addition to the literature to which I have called your attention, did Roche-Organon or Ciba or any of these other companies supply you with literature in addition to this little brochure?

A. Do you mean the manufacturers' brochures?

Q. That is right; in addition to Defendants' Exhibit A, and I believe there are two others, probably D and E.

A. The Schering Corporation supplied us with other literature.

Q. How about Roche-Organon?

A. Roche-Organon only supplied us with literature pertaining to the product we were buying from them.

Q. I would like to invite your attention, Mr.

(Testimony of Martin A. Clemens.)

Clemens,—could this be marked for identification, please?

The Clerk: Government's Exhibit No. 18 for identification.

(The document referred to was marked Government's Exhibit No. 18 for identification.)

Q. (By Mr. Danielson): I would like to show you this document, Mr. Clemens, which purports to be a letter from Roche-Organon, and ask you if you have ever seen it before. A. I have.

Q. You received one of those from Roche-Organon, is that correct? A. That is correct.

Q. Did you read that, Mr. Clemens?

A. I did.

Q. Did it not make restrictions, Mr. Clemens, on the use to which you could put this literature which they distributed?

A. At that particular time, they did.

Q. And that was in July, 1947?

A. That is right.

Q. And what were those restrictions?

A. They told us not to give out too many of them.

Q. As a matter of fact, didn't they make it more strong than that?

A. They might have in the letter but they kept supplying us anyhow.

Q. I would like to invite your attention here to a phrase, "This pamphlet has been prepared for

(Testimony of Martin A. Clemens.)

dissemination to the medical profession exclusively." Do you remember such a statement?

A. That is right.

Q. Here is another, "All Roche-Organon products, with the exception of cytora, are strictly prescription items; literature, therefore, must be kept out of the hands of your customers. You would be breaking faith with your physicians to do otherwise. In fact, you might even endanger lives, for hormones are powerful therapeutic agents which must be administered [491] under strict medical supervision." You remember that, do you not?

A. I remember that; yes, sir.

Q. That was put out by the manufacturer of that drug, was it not? A. That is correct.

Q. And do you remember they also told you, "So pass along these facts to all your clerks: (1) Roche-Organon literature is for physicians only. (2) Keep Roche-Organon literature out of reach of your customers. (3) All Roche-Organon products (except cytora) bear an Rx legend on their labels, and therefore, may be dispensed only on a physician's prescription. (4) Don't give out literature with prescriptions for Roche-Organon products even when the patient asks for it"? Do you remember that?

A. I remember that in the letter but that is not what their agents told us to do.

Q. But you do remember this letter, do you not?

A. Yes, sir.

(Testimony of Martin A. Clemens.)

Q. You mentioned Ciba, did you not, that Ciba has put out some literature? A. Yes, sir.

Q. Are you familiar with this literature that Ciba puts out along with their hormonal products?

A. Some of it. [492]

* * *

Mr. Danielson: Your Honor, I should like to offer Government's Exhibit 18 for identification in evidence.

The Clerk: Government's Exhibit 18 in evidence.

(The document referred to was marked Government's Exhibit No. 18 and received in evidence.)

* * *

Q. I want to direct your attention, Mr. Clemens, to some other literature put out by Ciba. You have seen their little booklet entitled "Male Hormone Therapy," have you not, from Ciba's?

A. Yes, sir.

Q. And you have looked it over, have you not?

A. Yes, sir.

Q. Do you remember their statement, and I am quoting from page 146, "The use of androgens and the treatment of other conditions such as cryptorchidism, the 'male climacteric,' angina pectoris, ovarian dysfunction (functional uterine bleeding), dysmenorrhea and other gynocologic conditions is experimental and cannot be recognized until more conclusive evidence becomes available"?

And. again on the same page, "The male sex

(Testimony of Martin A. Clemens.)

hormone is contraindicated in the following conditions:

Sterility: Large doses may cause azoospermia since the hormone secreted by it tends to inhibit the gland which produces it."

And, again, "Carcinoma of the prostate: It is unwise to give testosterone propionate in these cases."

The Court: What carcinoma was that?

Mr. Danielson: Of the prostate.

Q. You have seen the literature put out by Ciba, "A summary of sterility sex hormone therapy," no doubt? A. Yes, sir.

Q. Did you notice on page 13 thereof contraindications, "Androgens are contraindicated——"

Mr. Elson: Just a moment. What is the date of that book? [494]

* * *

Mr. Danielson: The pamphlet from which I am about to quote is dated 1947 and, moreover, Mr. Clemens has stated he is familiar with it. I should like to question him about it.

The Court: He didn't admit that he was familiar with it at the time that these transactions involve.

Q. (By Mr. Danielson): Mr. Clemens, is it not true that this literature put out by the manufacturer is the type of literature you have been describing and with which we are now [495] dealing, distributed by the manufacturers through outlets from time to time in the course of their business transactions? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. And, in 1947, you received the 1947 information and, likewise, in 1948, you received the 1948 information, is that correct?

A. We received them; yes. [496]

Q. Inviting your attention to this booklet with which you have mentioned you are familiar, "Steroid Sex Hormone Therapy," you did have occasion to see this, is that not correct?

A. Just recently; yes.

Q. It was made available to you, however, a couple of years ago? A. That is right.

Q. And you are in the business of selling these hormones, are you not? A. That is right.

Q. In fact, you obtained the wording for your own literature from these various pieces of literature distributed by the manufacturer, did you not?

A. That is correct.

Q. Did you not take the trouble to notice that, on page 13 of this little pamphlet, with the heading "Contraindications——"

Mr. Elson: Wait just a minute, Mr. Danielson. You haven't shown yet that he read this, even though it might have been in 1947, prior to the time that any of these shipments were made.

Mr. Danielson: If your Honor please, it has been established, in the first place, that the defendant is familiar with the pamphlet; in the second place, that it was published [497] in 1947; third, it was received by him about that time, and, fourth, it was available and could have been read by him.

Mr. Elson: Whether he did or not is a question of fact.

(Testimony of Martin A. Clemens.)

The Court: I haven't heard any evidence that he received it in 1947.

Q. (By Mr. Danielson): I believe you testified, did you not, that you received this a couple of years ago? A. I believe I did.

Q. Well, did you?

A. I don't remember that book but, offhand, I have not gone through all of these booklets. I don't know when I received them. They shipped them to us but I don't remember the dates.

Q. You don't remember when you went through them for sure, then?

A. That is right. It is only recently I have been reading those booklets.

Q. Why have you started reading them recently?

A. Because of the government charges here.

Q. Have you changed that little pamphlet, "Male and Female Sex Hormones" recently?

A. I don't remember when I saw it last.

Q. Why did you not include, Mr. Clemens, those things, the statement relative to carcinoma and the statement relative [498] to sterility? Why did you not include those in your little pamphlet?

Mr. Elson: Just a minute. He says he doesn't recall having recently changed them.

Mr. Danielson: He has referred to Defendants' Exhibit A. That is one which I am confident Mr. Clemens recalls. The other pamphlets which have been mentioned—Mr. Clemens has testified he did receive this literature and did look at this pamphlet on Male Hormone Therapy.

(Testimony of Martin A. Clemens.)

The Witness: That deals with testosterone propionate and we don't have much to do with that.

Q. (By Mr. Danielson): How about androgens? Do they include methyl testosterone?

A. Yes; they include methyl testosterone.

Q. The statement so far as it applies to androgens would cover methyl testosterone?

A. That is correct.

Q. But you published no warnings as to the use of them, is that correct? A. No, sir.

Q. Now, you stated a while ago that you have been taking these hormones for some time. Do you take them under the supervision of a physician?

A. No, sir.

Q. How did you say you received this injection?

A. By a doctor.

Q. That has been going on for a year or two?

A. That is correct.

Q. And the doctor is still administering it, is that right? A. That is right.

Q. How come you consulted a doctor, Mr. Clemens?

A. I had no way of injecting it myself.

Q. You didn't ask the doctor for any device, then, I gather? A. No, sir.

Q. You told him what to do and he did it?

A. That is correct.

Q. He conducted no examinations at any time?

A. None whatsoever.

Q. And then you have no way of knowing whether you have any early or incipient carcinoma of the prostate, do you? A. No, sir.

(Testimony of Martin A. Clemens.)

Q. How did you get started taking these hormones, Mr. Clemens?

A. I just wanted to check to see what they would do.

The Court: Did you find out that they had the potency to do the things that the manufacturers suggested?

The Witness: Yes, sir; they do. [500]

Q. (By Mr. Danielson): Now, Mr. Clemens, you mentioned that you buy these hormones at nine out of ten drug stores without a prescription.

A. That is correct.

Q. Did you ever try Horton & Converse's?

A. Yes.

Q. Did you succeed?

A. Well, I can buy it there; yes.

Q. You happen to be a pharmacist, do you not?

A. That is right.

Q. Do you know whether a lay person can?

A. I wouldn't know.

Q. Have you tried it out at the Rexall Drug Stores downtown? A. Some of them.

Q. Some of them turned you down?

A. That is right. I don't give my credentials or anything.

Q. Can you name any one pharmacy down here that has sold you the hormones without knowing you are a pharmacist and [501] without a prescription? A. Any one pharmacy where?

Q. Downtown in Los Angeles.

(Testimony of Martin A. Clemens.)

A. Oh, sure; yes, sir. The one on the corner of Fourth and Broadway, two doors north, and there is one in the middle of the block between Fifth and Fourth on Broadway, and there is one on the corner of Fourth and Broadway.

Q. What is this store at Fourth and Broadway now? A. It is a little store——

Q. Is it a Rexall store?

A. No, sir. This is a regular drug store.

Q. What is the name of this drug store?

A. I don't recall the name. It is about three or four doors north of Fifth and Broadway, on the eastside of the street.

* * *

Q. Would you be more particular in telling us what this drug store is?

A. It is a little drug store about four doors north of Fourth and Broadway, on the east side of the street. [502]

Q. Fourth and Broadway or Fifth and Broadway? A. Fifth and Broadway.

Q. Do you know of any other reputable drug store downtown?

Mr. Elson: What do you mean by "reputable"?

The Witness: A drug store on the corner of Fifth and Spring, the Alexandria Drug Company, and a drug store on the corner of Fourth and Broadway, the Safety Drug Company.

Q. (By Mr. Danielson): And at those drug stores you can buy methyl testosterone without a

(Testimony of Martin A. Clemens.)

prescription and without being a pharmacist?

A. That is correct. [503]

* * *

Cross-Examination

(Resumed)

By Mr. Danielson:

Q. Mr. Clemens, when you were on the stand yesterday, I believe you did testify, did you not, that you are a pharmacist?

A. That is correct.

Q. You are licensed to practice your profession here in California? A. Yes, sir.

Q. Where did you go to school to study your profession? [505]

A. I didn't go to school to study it.

Q. But you did pass the State Board, or whatever it is called? A. That is correct.

Q. In your preparation as a pharmacist, you learned, of course, that a pharmacist deals with the public in his trade at all times, did you not?

A. Yes, sir.

Q. And that the pharmacist, by virtue of his type of business, has to deal with not only more or less innocuous remedies but, likewise, poisons, dangerous remedies and a wide quality of products, is that correct? A. That is correct.

Q. And that a pharmacist, in dealing with the public, has a duty at least not to wilfully deceive the public in its contacts, relative to these subjects, is that correct? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. And I imagine wilfully not to deceive—or you might say in good practice you would use good faith and confidence in dealing with the public, isn't that correct? A. That is correct.

Q. And you have been practicing pharmacy since about 1937, is that correct? A. 1927.

Q. And I presume that you, likewise, have not wilfully [506] deceived the public in your business, is that not correct? A. That is right.

Q. You have used good faith and confidence in all of your dealings with the public?

A. That is correct.

Q. And I presume that was true when you were in your hormone business, is that correct? You didn't wilfully deceive the public in the hormone business? A. No, sir.

Q. That was true at the time of the counts alleged in this information, in 1947 and 1948? You were still using good faith and confidence in your dealings with the public? A. Yes, sir.

Q. You were not wilfully deceiving the public?

A. No, sir.

Q. In this literature you passed out, that little pamphlet "Male and Female Sex Hormones," which is identified as Exhibit 1-A in the exhibits, and also several other exhibits, you didn't wilfully deceive the public there, did you? A. No, sir.

Q. And I presume that is true of all of your literature that you passed out, of any representa-

(Testimony of Martin A. Clemens.)

tions made to the public? You didn't wilfully deceive the public then? A. No, sir. [507]

Q. And you don't deceive the public today, for that matter, do you? A. No, sir.

Q. You still use good faith and good business during any dealing with the public?

A. Yes, sir.

Q. In all of your representations?

A. Yes, sir.

Q. Mr. Clemens, since you have been using good faith and confidence, I don't imagine you would object, would you, to having the court see some of the ads you put out to the public?

A. No objection. [508]

* * *

Mr. Danielson: For the record, I should like to have these marked for identification. I have a photostat of page 34 of the Los Angeles Daily News, dated October 15, 1947.

The Clerk: That will be Government's Exhibit No. 21 for identification.

Mr. Danielson: I have page 30 of the Los Angeles Times, Sunday, April 17, 1949.

The Clerk: That will be Government's Exhibit No. 22 for identification.

Mr. Danielson: And page 22, Part One of the Los Angeles Times for Wednesday, June 8, 1949.

The Clerk: Government's Exhibit No. 23 for identification. [510]

Mr. Danielson: And page 8-B, Los Angeles Daily News, Tuesday, July 5, 1949.

(Testimony of Martin A. Clemens.)

The Clerk: Government's Exhibit No. 24 for identification.

Q. (By Mr. Danielson): Now, Mr. Clemens, I invite your attention to Government's Exhibit No. 21 for identification, particularly to an ad in the right-hand column just above the middle of the page, relative to hormones, M. A. Clemens, Pharmacist. That is one of the ads that you caused to be published, is it not? A. That is correct.

Q. And you are aware, naturally, of the contents of that ad, isn't that correct?

A. That is true.

Q. Likewise, I invite your attention to Government's Exhibit No. 22 for identification, the lower right-hand portion of the page, an ad relative to male hormones, with the address of El-O-Pathic Pharmacy. That is one of your ads, is it not?

A. That is correct.

Q. And you are familiar with the contents of that ad? A. Yes, sir.

Q. And, likewise, in Government's Exhibit No. 23 for identification, in the lower left-hand portion of the page, another ad of the El-O-Pathic Pharmacy. Is that one of your [511] ads, Mr. Clemens?

A. That is correct.

Q. And you are, of course, familiar with the contents of that, are you not? A. Yes, sir.

Q. Then, again, on Government's Exhibit 24 for identification, a newspaper of July 5, 1949, I direct your attention to an ad at the lower left-hand por-

(Testimony of Martin A. Clemens.)

tion of the page. That is from El-O-Pathic Pharmacy. It is one of your ads, too, is it not?

A. That is correct.

Q. And you are aware of the contents of it?

A. Yes, sir; that is right.

Q. Now, Mr. Clemens, in publishing these ads, both those of recent date and the one back there in 1947, you were, again, you say, using good faith and confidence and were not misleading the public, is that not correct? A. That is correct. [512]

* * *

Q. (By Mr. Danielson): You testified yesterday, Mr. Clemens, that you have studied a booklet, "Summary of Steroid Sex Hormone Therapy," which was likewise published by Ciba?

A. I don't believe I said I studied it.

Q. You read it?

A. I glanced through it.

Q. Copyright, 1947. On page 13 of which is a statement to the effect:

"Contraindications," stating, "Androgens are contraindicated under the following circumstances:

"1. In the presence of carcinoma of the prostate particularly and carcinoma in general."

And a little further down, on page 13:

"Caution should be exercised in administering androgens over long periods to individuals with normal testicular function, since androgens have been reported as inhibiting [516] spermatogenesis."

You did read that, did you not?

(Testimony of Martin A. Clemens.)

Mr. Elson: Just a minute. Is that going to the question of credibility, Mr. Danielson?

Mr. Danielson: To a large part, yes.

Mr. Elson: Well, I submit that the question is objectionable on the grounds that I have already stated.

Mr. Danielson: It goes not only to the credibility, it does go to credibility, but likewise to one of our principal allegations, and that is that there is misbranding in this case because of false and misleading statements in the literature.

The Court: Objection overruled. The witness may answer.

The Witness: What is the question?

(Question read as follows: "You did read that, did you not?")

Mr. Danielson: I believe the witness has testified, yesterday, that he did, is that not correct?

A. That is correct.' [517]

* * *

Q. Very well. Now, Mr. Clemens, is it not a fact that in using good faith and confidence in dealing with the public, you would not wilfully mislead them as to any danger in these products of which you were aware?

A. No, I wouldn't. I checked all these dangers before I——

* * *

Mr. Danielson: Now, Mr. Clemens, you had no reason at the time of the publishing of these ads

(Testimony of Martin A. Clemens.)

and of the pamphlet, "Male and Female [518] Sex Hormones," which is Government's Exhibit 1-A and other numbers, you had no reason to believe that there was any danger involved in the use of these products, is that correct, of the male or female sex hormones?

A. I believe there was none. I checked with the state authorities but they gave me no reason to believe that there was.

Q. You had no reason to believe? A. No.

Q. And you apparently still have no reason to believe, is that correct? A. That is right.

Q. Now, Mr. Clemens, did you not formerly do business as Clark's Drugs and Sundries, Clark's Drugs or Clark's? A. Yes, sir.

Q. And likewise as M. A. Clemens?

A. That is right.

Q. Isn't it a fact that as far back as October 23, 1947, the fact of danger in these products was forcibly brought to your attention by the Federal Trade Commission?

A. I don't believe they brought the fact of danger. It was advertising the—it was the advertising they were interested in.

Q. And what was the nature of that warning? Wasn't it an order to cease and desist? [519]

A. That is correct.

Q. And what was the basis of that warning?

A. In what way?

Mr. Elson: Let me see it. [520]

* * *

(Testimony of Martin A. Clemens.)

Q. Now, Mr. Clemens, having received this, did you [524] subsequently issue this literature which by this very letter was restricted to physicians?

Mr. Elson: Just a minute. I object to that question on the grounds that counsel is placing a construction on the letter itself, which is something which this court can determine. If you will confine your question to did he subsequently put out this literature, I have no objection to it.

Mr. Danielson: I have no objection to phrasing that question in that manner, frankly, Mr. Elson.

Q. Did you? Having received this letter, did you subsequently put out the literature referred to in it?

A. They told me to ignore that letter.

Q. Well, did you? A. Yes.

Q. Why did you?

A. The manufacturers' managers told me to ignore that letter, that was merely put out to appease the medical profession, and they kept supplying us with that literature from then on.

Q. You mean to say that the agents of Roche-Organon issued this letter and then came around and told you to disregard it?

A. Not the agents. That came from the company's offices in Nutley, New Jersey. The local agents here told me to ignore the letter and they kept supplying me with literature as [525] long as they had it.

Q. That is, you mean contact men for this company?

(Testimony of Martin A. Clemens.)

A. The general managers of this company, yes.

Q. Told you to ignore it?

A. Yes. They put this letter out so that it would have that action on the medical profession, and they told me not to pay any attention to it.

Q. (By Mr. Danielson): What was the purpose of the letter, then?

Mr. Elson: Wait a minute. I object to the question. What was the purpose of the letter, that is asking for a bald conclusion on the part of the witness.

Q. (By Mr. Danielson): Well, what did they tell you was the purpose of the letter?

Mr. Elson: What did who tell him?

Mr. Danielson: These contact men of Roche-Organon.

A. They had to keep their product council-accepted with the medical profession, that they still had to have the outlet counciled.

Q. In other words, this was just sort of a front to make it all sound very legitimate, is that correct?

A. Well, I don't know what opinion you have of it.

Q. That was the net effect of it, was it not?

A. They told me to continue passing out and selling the product. [526]

* * *

Q. (By Mr. Danielson): Well, having received this letter, you nevertheless did issue the literature?

A. Yes, I did. I was told to ignore the letter.

(Testimony of Martin A. Clemens.)

Q. Even though the letter says to do so would be breaking faith with the physicians, is that not correct? [527]

* * *

Q. (By Mr. Danielson): Did you issue these products back at this time, 1947 and 1948, with or without a prescription, Mr. Clemens?

A. Without.

Q. And that is true today, I presume, is that not correct? A. That is correct.

Q. Mr. Clemens, directing your attention now to the product Menformon Dosule, that is Roche-Organon product? A. That is right.

Q. I show you a photostatic copy of Government's Exhibit 3-A which purports to be a package of Menformon Dosules. A. That is correct.

Q. You are familiar with this label, I presume?

A. Yes, sir.

Q. You are likewise familiar with the paragraph, "Caution: To be dispensed only by or on the prescription of a physician"? A. Yes, sir.

Q. And that label has been carried on the package, was carried on the package during 1947 and '48, was it not, Mr. [528] Clemens?

A. Yes, sir.

Q. But you sold without a prescription, nevertheless? A. That is correct.

Q. There is one more thing, Mr. Clemens: Mr. Clemens, yesterday I asked you a question——

Mr. Neukom: While he is looking for that, I would like to offer in evidence newspaper advertise-

(Testimony of Martin A. Clemens.)

ments. We at one time offered them and then we withdrew them, and they are Exhibits 21, 22 and 23.

Mr. Elson: I am going to object to them on the same grounds I objected to them before. [529]

* * *

The Court: The ruling on the admissibility of the report of the State Board, which was offered yesterday, is set aside in view of the present offer. The report of the State Board of Pharmacy will be admitted. As to these advertisements, I don't care to go much further with a matter that is in its nature, in large part advertising but I will go this far with the report that you offered, Mr. Elson, and these four newspapers——

Mr. Elson: In view of that, I will withdraw my objection to the newspaper articles for the purpose stated by Mr. Neukom.

Mr. Neukom: Very well.

The Clerk: Those are Government's Exhibits 21, 22, 23, and 24 in evidence. [531]

* * *

Q. (By Mr. Danielson): Mr. Clemens, yesterday I asked you, at page 477 of the transcript, "Q. Have you ever been convicted of a felony, Mr. Clemens? "A. No, sir.

"Q. Never? A. No, sir."

Now, Mr. Clemens, it is possible that there is a mistake here but are you not the M. A. Clemens who appeared before Judge Leon Yankwich of the United States District Court here in Los Angeles, on April 12, 1937? A. That is correct.

(Testimony of Martin A. Clemens.)

Q. And what was the nature of that charge? Was it not the selling of a compound containing a derivative of opium, to wit, morphine, in a preparation known as Pine Cherry and Guaiacol Compound——

A. That is a cold remedy.

Q. ——in violation of Title 26, Section 1044, of the United States Code? [532]

A. That is right.

Q. And the result of that was a conviction, was it not?

A. It was a fine on a misdemeanor charge. We discussed it with the Judge.

Mr. Danielson: The section of the code, 1044-A, I believe the court will take judicial notice of, is a felony.

The Witness: It was reduced. We talked that over with the Judge. There were maybe two or three hundred druggists up there at one time. There was some technicality of whether the syrup could be sold or not. Thrifty, Sontag and several others, all of them, were convicted and the Judge ruled it was a misdemeanor and find us $200.

Mr. Danielson: Very well. As I mentioned, on that there could possibly be a mistake.

No other questions. [533]

* * *

Mr. Elson: I have no other questions of Mr. Clemens.

The Court: May I ask you, did you acquire these

(Testimony of Martin A. Clemens.)

drugs in question by direct purchase from the manufacturers and shipment from them directed to you or did you purchase them through some sales agency, from a supply kept by such agent or agents here?

The Witness: We purchased them direct from the manufacturer. Some of the time the manufacturer would ship them out to their agents and they, in turn, would deliver them to us but always we paid directly to the manufacturer.

The Court: And you ordered them directly from the manufacturer?

The Witness: Yes, sir.

The Court: Did each of these three concerns from whom you bought these goods have local sales agencies?

The Witness: Yes, sir; and daily contact. [534]

* * *

Mr. Elson: Dr. Fakehany, please.

GEORGE E. FAKEHANY, M.D.

called as a witness for the defendants, being first duly sworn, testified as follows:

The Clerk: Your full name, Doctor?

The Witness: George E. Fakehany (spelling same), M.D. [535]

* * *

Direct Examination

By Mr. Elson:

Q. Dr. Fakehany, you hold a degree of Doctor of Medicine, do you? A. I do.

(Testimony of George E. Fakehany, M.D.)

Q. Where did you attend school?

A. Loyola University, Chicago.

Q. Did you graduate from there?

A. I did.

Q. In what year? A. 1937.

Q. Did you receive any honorary degree with your M.D. degree? A. I graduated cum laude.

Q. In medicine? A. Yes, sir.

Q. Did you intern at any hospital?

A. I did.

Q. Where?

A. Los Angeles General Hospital.

Q. For how long?

A. A two-year period.

Q. Were you a resident physician at any hospital for any period of time? A. I was.

Q. What hospital was that? [536]

A. The Good Samaritan Hospital.

Q. Here in Los Angeles? A. Yes, sir.

Q. In what year? A. In 1939.

Q. And you took the State Board in California in what year? A. 1938.

Q. And passed it at that time? A. I did.

Q. Are you admitted to practice medicine in any other State than California? A. I am.

Q. What State? A. Ohio.

Q. Are you a member of any medical associations?

A. I am a member of the Los Angeles County Medical Association and the Hollywood Academy of Medicine.

(Testimony of George E. Fakehany, M.D.)

Q. Are you engaged in general practice?

A. I am.

Q. In your practice, are you a medical consultant or examiner for any large companies?

A. I am.

Q. Will you state for what companies?

A. I am the medical examiner for Technicolor Motion [537] Picture Corporation, a large Hollywood manufacturing concern, and Samuel Goldwyn Studios and RCA.

Q. That is the Radio Corporation of America?

A. Of America. I think those are the largest.

Q. In this case there has been charged that methyl testosterone in tablet form, among other things, 25 milligrams to be taken one to two tablets daily, is dangerous in that that product of that dosage may accelerate the growth of an incipient carcinoma of the prostate and may cause sterility. Now, keeping that in mind, in your opinion, would it be possible for you to diagnose or discover an incipient carcinoma of the prostate?

A. Incipient carcinoma of the prostate gland represents the very beginning of a prostatic carcinoma, and it is most difficult at this time to diagnose carcinoma of the prostate gland.

Q. About how large would the carcinoma of the prostate have to be before you would be able to feel it by palpation?

A. It would have to be at least the size of a grape or acorn.

Q. Why is that?

(Testimony of George E. Fakehany, M.D.)

A. If it was any smaller, it would be lost in the substances of the prostate gland. In the very beginning, it is impossible to differentiate the cells from the normal prostatic tissue. [538]

Q. Is the prostate gland surrounded by a covering of any kind?

A. It has a thick capsule.

Q. Does that have any effect on your ability to feel it by palpation?

A. In examination of the prostate gland, particularly through the rectum, it must necessarily be made through the thick capsule surrounding the prostate gland and you try to determine what is within the capsule.

Q. Have you in your practice ever used a blood or a urine test to detect an incipient cancer?

A. I never have.

Q. Do you know of any practitioners in general practice who do that?

A. Ordinarily, doctors in general practice do not use this type of examination.

Q. What examinations are there, besides palpation, with which you are familiar, and that are commonly used by doctors in this locality in detecting an incipient carcinoma of the prostate, other than by palpation?

A. There are none that I know of.

Q. Have you read the literature from time to time concerning the relationship of the use of testosterone to prostatic cancer? A. I have. [539]

(Testimony of George E. Fakehany, M.D.)

Q. And what has that literature, in general, consisted of?

A. The literature suggests that methyl testosterone aggravates or might possibly aggravate a carcinoma of the prostate gland.

Q. Is the literature uniform in that suggestion or what?

A. It certainly is not uniform. It is merely suggestive and suggests that you use caution because of the possibility of carcinoma of the prostate. However, there is much confusion in the literature on that subject. [540]

* * *

Q. Doctor, have you ever encountered in your practice a cancer of the prostate? A. I have.

Q. In your practice, approximately how many do you encounter per year, we will say?

A. Well, I would say, on an average, about one every two years.

Q. And you have encountered that by rectal examination?

A. Well, I picked up some by rectal examination but very frequently by X-ray.

Q. In a physical examination?

A. A general physical examination.

Q. Is it possible for you to find a cancer of the prostate?

A. It is if it is far enough advanced.

Q. In your practice, approximately how many physical examinations of men do you estimate that you have given?

(Testimony of George E. Fakehany, M.D.)

A. Well, during the war, I gave thousands of physical examinations. All the large manufacturing plants in Hollywood insisted on physical examinations. I was the doctor that gave them for the Hughes Aircraft Corporation and we did on an average of 20 to 25 physical examinations a day for them.

Q. With all of those examinations, did you find cancer [541] of the prostate frequently or infrequently? A. It is very infrequently found.

* * *

Q. (By Mr. Elson): Before I get to that, I want to lay some more foundation. Have you prescribed in your practice testosterone for people?

A. I have.

Q. How frequently would you say on an average do you prescribe it?

A. I would say on an average of once a day.

Q. In your practice, have you ever encountered any what you considered adverse results as the result of testosterone administration?

A. I never have.

Q. Now, on the basis of what you have read and your experience, do you have an opinion as to whether testosterone will accelerate the growth of an incipient carcinoma of the prostate?

A. I really have no opinion in that respect. I know that there are many doctors that think that it might. Much of the literature suggests that it might and there are many [542] doctors that, frankly, don't know, and I think I am one of them.

(Testimony of George E. Fakehany, M.D.)

Q. But you have never encountered any adverse results from administering testosterone once a day during your practice?

A. I have never had a bad result from it.

Q. As to the subject of sterility, have you read in the literature anything about the subject of sterility in relation to the administration of testosterone? A. I have.

Q. Based upon your experience in the administration of it and what you have read, do you have an opinion as to whether or not the administration of testosterone will cause sterility?

A. I might state that the administration of testoserone will lower the sperm count and for that reason we don't like to give the testosterone over a long period of time to one individual. In other words, we give it for possibly two or three months and then leave them rest a while, due to the fact it does lower the sperm count. But as far as actually producing sterility, I doubt that it does.

Q. In your opinion, do you consider that testosterone is a dangerous drug, based upon your experience?

A. I have had no danger with it at all. I have experienced none. [544]

Q. The usual age of the man to whom you administer testosterone is about what?

A. Between 50 and 65.

Q. Do you consider that the factor of sterility or fertility with a man of that age, who would other-

(Testimony of George E. Fakehany, M.D.)

wise, in your opinion, require testosterone, would be a factor? A. I don't think so.

Q. In the information here it is alleged—or I am going to ask you this. Assuming that a man was suffering from a male sex hormone deficiency, in your opinion, would 25 milligrams of testosterone or 50 per day, methyl testosterone, stimulate the growth—assuming that he has a male sex hormone deficiency, would it stimulate the growth and development of the sex organs?

A. I don't think that it would.

Q. If a man was a hypogonad, do you think testosterone would stimulate his sex organs?

A. It might in that case.

Q. And a hypogonad is a person suffering from a hormone deficiency? A. That is correct.

Q. If a person is suffering from a male sex hormone deficiency, would the administration of testosterone stimulate the growth and development of the male characteristics, such as the distribution of hair, muscular development and depth of [545] voice? A. I think it would.

Q. That is, with the average individual, or are you distinguishing a hypogonad from the average individual?

A. I presumed you were referring to a normal individual.

Q. Let's speak about a hypogonad for a moment. Let's say there is no distribution or a very incomplete distribution of hair, very incomplete muscular development, a lack of depth of voice. Do you think

(Testimony of George E. Fakehany, M.D.)
testosterone would stimulate the growth of those particular elements I have named?

A. It might in an individual——

Q. Let's take an individual who has a normal distribution of hair on his body. If he takes testosterone, it wouldn't make hair grow all over him, would it? A. Certainly not. [546]

* * *

Q. (By Mr. Elson): What do you give testosterone for?

A. Testosterone is commonly given to a patient that is of the age of anywhere from 45 to 70, that complains of these following symptoms, or a combination of them: Unusual weakness, loss of memory, inability to concentrate, nervousness, general fatigue. He may have any combination of these symptoms. Particularly is it given when there is no evidence of any other pathology, for instance, when there is nothing else you can point the symptoms to. We presume that the individual is suffering from male hormone deficiency or going through the change of life.

Q. In your practice, when a person complains of those symptoms, what do you usually do?

A. Well, I usually talk with him for a few moments to try to determine if there is anything else that bothers him, for instance, if the patient has a bad heart or had had any type of examination or medical care in the past. And, if I can readily determine that the patient doesn't have any organic pathology, I will prescribe or inject male hormones.

(Testimony of George E. Fakehany, M.D.)

Q. And do you give it a try for a certain period of time? A. I do.

Q. Over what period of time do you consider it to be effective for things like that?

A. I usually prescribe about a month's supply and, if [547] the patient is going to get any benefit from it at all, he should come in within that month.

Q. With the great number of people for whom you have prescribed testosterone as you have stated, have you found many of them have been relieved of those symptoms?

A. Many of them and some of them have not.

Q. And, when they have not been relieved, what do you conclude?

A. I conclude that the hormones were ineffective in their particular case.

Q. In other words, that they were not suffering from hormone deficiency? A. Apparently not.

Q. In the practice of medicine, is that an unusual procedure? A. I think it is quite usual.

Q. Is it usual, when a person complains of certain symptoms, for a doctor to conclude that maybe a certain course of treatment will be beneficial and try it and see whether or not it works?

A. It is common practice.

Q. In other words, it is, to a large extent, a method of trial and error, is it not?

A. That is correct. [548]

Q. (By Mr. Elson): Now, for the purpose of determining the efficacy of testosterone, testosterone or let us include estrogens as well, as to their harm-

(Testimony of George E. Fakehany, M.D.)

ful effect, if any, in your opinion, would a large number of tests have to be conducted before it could be considered as proof that harm was to result from the taking of it, or just a few tests, would they suffice? A. I take no tests at all.

Q. No, no, no. I understand that, but I mean from an experimental standpoint, we will say the university. A. Oh, I see.

Q. (Continuing): Or the experimental hospitals, that is what I have reference to.

A. Naturally, the more tests that can be performed to determine whether or not a drug is dangerous, the more the better.

Q. Would you consider that two or three or four tests over a period—wait a minute—that two or three or four instances in which deleterious results to the patient follow the administration of a certain drug would be proof that that drug would in individuals cause damage?

A. You mean two or three or four instances in a country——

Q. Over 15 years.

A. ——in a country of the size of the United States? [549]

Q. Yes. A. I would say certainly not.

Q. In other words, that could be as effective with almost any drug, could it not?

A. I think so, certainly.

Q. Isn't that true with simple home remedies such as, well, let us take aspirin?

(Testimony of George E. Fakehany, M.D.)

A. That might be true of anything, it might be true of common table salt.

Q. Now, then, in his testimony, Dr. Huggins the other day (pages 286 and 287) stated as follows:

"Occasionally we are forced to do things to human beings, in a few cases to make a few observations that are not strictly in the patient's best interests. We do nothing that will do permanent harm or at least we attempt to, in medical investigation, but we found that the removal of the gonads would cause, in a very spectacular way, widespread cancer of the prostate to shrivel up, to shrink and to disappear.

"Then, we had to try the converse and we gave testosterone to patients with mild cancer of the prostate and when that was done, either 10 milligrams of methyl testosterone a day given by mouth or 5 to 10 milligrams to 25 milligrams of testosterone injected, then the patient became very ill indeed, and had to take to his bed."

Now, in your practice, is it your practice to experiment [550] with your patients in such fashion?

A. We do not experiment with patients. That is done in laboratories.

* * *

Q. (By Mr. Elson): Doctor, what do you strive for in the treatment of the ailments of your patients or their conditions? [551]

A. Well, we try to get them well, or at least improve their condition.

Q. Now, another thing that Dr. Huggins stated—and you went to school in Chicago, although not the

(Testimony of George E. Fakehany, M.D.)

University of Chicago—at page 294, I believe it was Dr. Huggins who was stating that—oh, I think I will let that go. It is not important enough anyway.

Now, on the subject of impotence, you find impotence in persons on occasions to be psychogenic in origin? A. I do. I certainly do.

Q. Do you find impotence on other occasions to be of some origin other than psychogenic?

A. Yes, sir.

Q. Have you prescribed testosterone for patients who complained of impotence? A. I have.

Q. And have you encountered any good results or adverse results on that subject, afterward?

A. I have had occasion of good results.

Q. The other day, one of these doctors, Dr. Heckel, stated, in answer to a question by the court, page 173, as follows: The court asked this question:

"The next thing I want to know, then, is assuming that they have the normal amount," that is an individual with a normal sperm count, "what, if you know, would be the effect [552] on them as to an increased stimulation?" That is by the administration of testosterone, and the answer was this:

"It would do two things. First, it would destroy the seminiferous tubules of the testes and, 2, it would aggravate the growth and dissemination of prostatic cancer."

Do you agree with that statement or do you disagree with it, at least as to the destruction of the seminiferous tubules? You have testified as to the other.

(Testimony of George E. Fakehany, M.D.)

A. It very rarely has been mentioned to do that; and frankly, I don't know whether or not it does. I don't think anyone knows whether it destroys the seminiferous tubules. I don't know how they could prove it.

Q. Why do you say that?

A. I don't know how in the world the individual could prove it, particularly when you are dealing with human beings.

Q. Now, then, on page 176, this doctor also was asked, "How is male hormone deficiency in any person determined?" And he answered this: "Determined by, first, a careful history, No. 2, careful physical examination and No. 3, there are some laboratory tests that will aid in diagnosis, such as the estimation of 17 ketosteroids in the urine."

Is it your practice when a person complains of the symptoms such as we have described, for you to submit the person to such test, to determine whether he has a hormone deficiency, before prescribing testosterone? [553]

A. I submit them to no tests.

Q. Did you ever hear of an instance of any doctor in this locality who does submit them to such tests as that?

A. Well, there are very few that do, if any. None that I know of.

Q. Now, then, Dr. Heckel stated, page 182, in speaking of prostatic cancer, "In the majority of men, the diagnosis in the majority of instances is by rectal examination.

(Testimony of George E. Fakehany, M.D.)

"Q. Can it be detected in early stages?

"A. Yes. But, in early stages, early prostatic cancer, it may be necessary to supplement the rectal examination with a biopsy."

Mr. Danielson: Excuse me. What page is that?

Mr. Elson: 182. Q. (Continuing): Now, in your practice, in determining whether a man has a male hormone deficiency, to enable you to decide whether to prescribe testosterone, have you ever performed a biopsy on his testicles?

A. I never have.

Q. Have you ever heard of any doctor, in every-day practice, who has done such a thing?

A. I have not.

Mr. Danielson: Just a moment. I believe that is an error, on page 182. It is not a biopsy on the testicles. It is a biopsy on the prostate, rather than on the testicles.

Mr. Elson: Well, all right. [554]

Q. Biopsy on the prostate, have you?

A. I have never done one.

Q. Have you ever heard of other practitioners at least in this locality performing such an operation for the purpose of determining whether there was a prostatic cancer?

A. Yes, biopsy of the prostate gland. If a doctor suspects that a patient has or might have a prostatic cancer, carcinoma of the prostate gland, he may do a biopsy.

Q. But, is it common practice to do a biopsy

(Testimony of George E. Fakehany, M.D.)

when one has not been able to find it by a rectal examination? A. No, certainly not.

Q. How would you go about, then, to perform a biopsy of the prostate?

A. Well, biopsy on the prostate gland is commonly done by inserting an instrument through the penis and cutting a piece of the prostate gland.

Q. And then subjected to test?

A. It is a laboratory test, by a pathologist.

Q. In medical practice, as you have found it, are you able to say whether a large percentage of medical work is specific for certain conditions, or whether it is based on hypothesis, conjecture and hopes?

A. Well, some of our work is specific and exacting, but a large part of it is based on trial and error.

Q. Would you be able to form an estimate as to approximately [555] what percentage would be based on trial and error?

A. Well, I would say half of it.

Q. Now, then, another witness, Dr. Glass, stated here that in his opinion——

Mr. Danielson: What page?

Mr. Elson: Well, I don't know. I haven't any recollection as to any particular page, but he stated that in substance, that estrogen was an absolute prerequisite to the growth of a breast cancer. Do you agree with that opinion? A. I do not.

* * *

Q. (By Mr. Elson): Why don't you agree with that opinion?

(Testimony of George E. Fakehany, M.D.)

A. Well, the reason I don't agree with him is that he has never been able to prove it, nor has any doctor been able to prove it. I would like to see it, if they can prove it, but it is merely a hypothesis so far as I am concerned, it is merely his opinion.

Q. In your opinion, would a dosage of 5 milligrams a day of alpha estradiol be dangerous in eccelerating the growth of a breast cancer, cervix or uterus? [556]

A. No. Frankly, not my opinion, but I know that some doctors think that it might.

Q. Have you ever administered alpha estradiol or estrogen? A. I have.

Q. Have you ever encountered any adverse results from the administration of them?

A. I have never.

Q. Have you ever administered dosages of that size or larger?

A. That size and larger.

Q. What is your common practice as to dosages larger or of that size?

A. Well, that is an accepted dosage.

Q. In cases with .1 milligram of alpha estradiol to be taken three per day, for 10 days and thereafter one per day, in your opinion, would that dosage be dangerous in accelerating the growth of a breast cancer, servix or uterus, that is .1 milligram?

A. .1?

Mr. Danielson: Will you repeat the dosage again, Mr. Elson?

Q. (By Mr. Elson): Three, which would be 3 tenths per day.

(Testimony of George E. Fakehany, M.D.)

The Witness: 3 tenths?

Q. (By Mr. Elson, Continuing): For a period of 10 days [557] and thereafter 1 tenth per day.

A. Well, frankly I would use it, regardless. I know this, that the literature warns that it might do those things, but inasmuch as they have never been able to show anything concrete in this respect, I continue to use it until they can prove that it does or until my experience shows me that it does.

Q. 1 tenth of a milligram is very small, is it not?

A. You mean 1 tenth of a milligram of alpha estradiol?

Q. Yes. A. It is.

Q. Do you have any opinion as to whether or not 1 tenth of a milligram taken three times a day, as I have just mentioned, and then one per day after 10 days, is enough to be effective or ineffective?

A. Well, I think that should help a patient.

Q. Well, in regard to these dosules that are used for breast development, I show you here Government's Exhibit 3 which pertains to Count 3 and it is a photostatic copy of the label on the dosules that are involved here. I wonder if you would read that?

Mr. Sturzenacker: Here is the original. He can read it a little better.

The Witness: This is the original.

Mr. Neukom: What exhibit? [558]

Mr. Struzenacker: No. 3.

Q. (By Mr. Elson): Have you ever used such a product? A. I have.

(Testimony of George E. Fakehany, M.D.)

Q. With what result?

A. Well, frankly, ambiguous results.

Q. You mean it works in some cases and doesn't in others?

A. Well, I would say that an occasional patient thought that they experienced a response from it, but I have had many unsatisfactory results from it.

Q. What do you mean, unsatisfactory?

A. Well, it just didn't seem to do anything.

Q. Is that unusual with almost anything?

A. Well, naturally, a lot of drugs will produce some favorable results—or no results, I will put it that way.

Q. And the same would be true with testosterone if a person was not suffering from a hormone deficiency? A. That is correct.

Q. By the way, have you ever taken any testosterone yourself? A. I have.

Q. For how long, or when do you take it, put it that way?

A. Well, practically whenever—once in a while the drug houses send us what we call their physicians' samples, [559] to try ourselves, you know, and I usually consume those myself and on occasions I give them to patients.

Q. Did you take them for any particular purpose?

A. Well, we take them naturally because we think that they will stimulate us and make us feel better, possibly stimulate your libido.

(Testimony of George E. Fakehany, M.D.)

Q. Have you noticed that they had any such effect? A. Well, I thought they did.

Q. Now, then, Doctor, in connection with this .1 of a milligram of alpha estradiol, the complaint alleges that it may cause uterine bleeding and, by the way, did you ever encounter any adverse results from taking testosterone? A. I never did.

Q. (By Mr. Elson): Now, Dr. MacDonald testified, at page 129, around in there, and the substance of his testimony was this, that the taking of that quantity of alpha estradiol might cause bleeding, uterine bleeding, and that the danger of it would be that he would be unable to know whether the bleeding was as a result of a malignancy or something else. Now, would you consider that if a woman took alpha estradiol and encountered uterine bleeding, that that would be a dangerous thing to her? A. It is a warning sign.

Q. Yes, but let me put it this way: Is it unusual for a woman who is suffering from a malignancy to bleed? [560] A. It is quite usual.

Q. That is, as a matter of fact, one of the things that you look for, isn't it? A. That is correct.

Q. Would it be fair to say, then, Doctor, if a woman bled and came to you, regardless of the cause of her bleeding, that she had been endangered or helped in the sense of enabling the doctor to discover some malignancy or something wrong with her?

A. I don't understand your question.

(Testimony of George E. Fakehany, M.D.)

Q. Here is a woman who has taken alpha estradiol. She commences to bleed.

A. How old is the patient? Is she past the menopause?

Mr. Elson: No. Any patient. She comes to the doctor and complains, says that she is bleeding, the doctor asks her what she has been taking and she says alpha estradiol, .1 of a milligram. Do you think that the mere fact that that estradiol might have caused uterine bleeding was dangerous to that woman's health? A. No, I do not.

Q. Why?

A. Well, naturally, if a woman is bleeding, you are going to stop the use of the drug, but we know this, that many times, when you do start the use of estrogen on patients, they will bleed, and we always discontinue the use of it in [561] those particular cases, because this bleeding very often signifies that they already have a carcinoma of the uterus. Many times they will bleed and they do not have a carcinoma of the uterus, but, due to the fact that sometimes they do bleed when you use the female hormones, you always discontinue the use of it.

Q. But the fact that they do bleed, in your opinion, is not a dangerous thing to their health?

A. No. Certainly not. If they do bleed, we usually do a curettement to determine if there is a cancer there.

Q. Doctor, you mentioned in the early part of

(Testimony of George E. Fakehany, M.D.)

your testimony, I think, about the male going through change of life.

A. That is correct.

Q. Is that more ordinarily known as the male climacteric?

A. Well, that is a question of much discussion in literature. The female we definitely know has a menopause. They definitely go through a change of life and the symptoms there are very pronounced in most cases, and they occur at a certain age, and the symptoms are more or less uniform. However, in the male, no such condition exists. It doesn't come at a certain age. The symptoms might vary, and for this reason, some of the literature suggests that the male does not have a climacteric; others suggest that they do have and it is between [562] the ages of 50 and 60 and the symptoms are so and so, and such and such. But, for the most part, the literature suggests that the male does go through a change of life.

Q. And have you found that men in those decades such as you mention, who complained of these symptoms, were benefited by the administration of testosterone?

A. Not all of them. Many of them were.

Q. But many of them were and some of them weren't? A. That is true.

Q. But would you conclude from those that were not, that they were not suffering from a hormone deficiency? A. That is correct.

(Testimony of George E. Fakehany, M.D.)

Q. In other words, they were not going through change of life or a climacteric?

A. At least their symptoms were not from that.

Mr. Elson: Cross-examine.

Cross-Examination

By Mr. Danielson:

Q. Doctor, let us assume from the beginning that in the treatment of your patients, you do try to benefit them. A. I certainly do.

Mr. Danielson: So we can dispose of that point right now.

Mr. Elson: I did not get your question.

Mr. Danielson: That I will say that the doctor does try [563] to benefit his patients in treating them; there is no other motive.

Q. Doctor, you studied at Chicago, I believe, is that correct? A. I did.

Q. I gather that you are possibly acquainted with Dr. Charles Huggins, at least by reputation.

A. Yes, sir.

Q. Do you consider him to be an authority in his field?

A. Yes, he has done a lot of work. I don't agree with everything he has done, but he has done some good work.

Q. You consider him, however, to be an eminent authority in his field, do you not?

A. Yes, he is considered to be an eminent authority.

(Testimony of George E. Fakehany, M.D.)

Q. Are you acquainted, either personally or by reputation, with Dr. Elmer Belt of Los Angeles?

A. Yes, I know Dr. Belt.

Q. Do you know him personally?

A. Well, yes, not too personally. He is an acquaintance.

Q. Do you consider Dr. Belt to be an authority in the field of neurology?

A. He is considered a good, competent urologist.

Q. And you likewise consider him that, I presume? [564] A. I do.

Q. Now, in Chicago do you know, by any chance, Dr. Norris J. Heckel of the University of Illinois?

A. No, I don't know him.

Q. You do not know him? A. No, sir.

Q. Are you familiar with his writings?

A. I have seen many of his writings.

Q. He is likewise considered to be an authority in this particular field, is he not?

A. I think he is.

Q. And lastly, are you acquainted or do you know Dr. Ian Macdonald, a local doctor?

A. Yes, I know Dr. Macdonald.

Q. He is likewise considered to be an authority in his particular field?

A. He is a urologist. I think he specializes in cancer, doesn't he?

Q. That is correct, female, I think.

A. Yes.

Q. He is a member of the Therapeutics Trials Committee, is he not? A. I believe he is, yes.

(Testimony of George E. Fakehany, M.D.)

Q. Now, Doctor, you mentioned that you do not conduct any experiments with your patients. May I ask you this: Do [565] you personally do any clinical research work?

A. Well, I think every doctor considers his own practice more or less research.

Q. That is in his field?

A. Individual research, that is correct.

Q. In either the field of the prostate or the testes or in the female genitalia or in endocronology, is that not correct? A. That is correct.

Q. Doctor, are you a urologist by specialty?

A. I am not.

Q. Are you an endocronologist?

A. I am not.

Q. Or a gynecologist?

A. No, but I practice all three.

Q. As a general practitioner?

A. As a general practitioner.

Q. You are a general practitioner. Now, Doctor, you have testified that you are a medical examiner, either are or were, or you have been, I do not recall, either or both? A. I am.

Q. You are a medical examiner for Technicolor, Goldwyn, RCA, I believe at least during the war you mentioned Hughes Aircraft?

A. Yes, Hughes Aircraft. [566]

Q. What were your general duties as such?

A. Well, we do pre-employment physical examinations on people seeking employment.

(Testimony of George E. Fakehany, M.D.)

Q. Is this a general physical examination?

A. General physical examination, that is correct, and——

Q. And is that your——

* * *

The Witness: And actually we take care of all their industrial accidents, in other words, if anyone is injured at the plant or sick at work, we take care of them.

Q. (By Mr. Danielson): That is, people who also complain or become ill while at work?

A. While at work, that is correct. We do 100 per cent of that now, and we do a large portion of their private practice. Of course, many of them have their own doctors. Some of them haven't. Usually those that haven't will go to the company doctor.

Q. You have your own offices, do you, and these various concerns refer their personnel to you?

A. Yes. They send their work to me, because it would be impossible to be at all of them at the same time.

Q. Yes. I gather that would be correct. [567] In this connection, do you call that industrial medicine?

A. Well, industrial medicine just refers to the industrial accidents, but it is actually private medicine, private practice.

Q. Well, in connection with these referrals by these three or four or more companies for whom

(Testimony of George E. Fakehany, M.D.)

you work, you do not in that particular practice handle any chronic cases, is that not correct?

A. Yes, we do have a few chronic cases. Of course, for the most part, employees are younger people.

Q. They are on the job? A. That is right.

The Witness: I was going to say, for the most part, people that are working are younger people and healthy people.

Q. (By Mr. Danielson): I thank you for bringing that up, as that takes me right to my next point. I was going to ask you, what is the average age of these persons whom you examine physically?

A. That varies, too. Now, of course the average age is younger than it was during the war. During the war it was anywhere from 17 or 18 to 80 or 85.

Q. But, under the present circumstances?

A. Under the present circumstances, I would say that the average is from 18 to I would say 50, maybe an occastional [568] in the 60s.

Q. The bulk of them are in the younger age groups?

A. In the younger age groups, that is correct.

Q. Let us say the upper 'teens or in the 20s or 30s? A. For the most part, yes.

Q. Thank you. Now, Doctor, how big is a prostate, a normal prostate?

A. Let's see, I will try to compare it. I would say the normal prostate gland is the size of a normal plum.

(Testimony of George E. Fakehany, M.D.)

Q. The testimony has been here, I think you may agree with this, by Dr. Belt, that the normal prostate is about the size of a chestnut. Would that be approximately correct?

A. A chestnut, well, I am not too familiar with chestnuts.

Q. Well, I will go along with you on the plum.

A. Okay.

Q. I am not too familiar with the chestnuts myself. A. All right.

Q. There are lots of plums, of course. About how big?

A. I would say about this round (indicating).

Q. That is the equal of about how round?

A. In diameter, the size of a silver dollar.

Q. A silver dollar, you would say?

A. That is correct.

Q. Well, then, before you can detect a carcinoma by [569] palpation, it would have to be the size of a grape or acorn. That would be getting up to about a third or fourth of the size of the prostate.

A. No.

Q. Maybe almost half the size of the prostate?

A. Well, I would say it would have to be, well, about a quarter of the size of the gland, before you could feel it. I wouldn't say that I could feel one any smaller than that. Maybe there are those that can, but I certainly would not be sure of anything that I felt any smaller than that.

Q. What is the purpose of this palpation examination?

(Testimony of George E. Fakehany, M.D.)

A. The purpose of the palpation is to determine the size and configuration of the prostate gland, and to see if there are any stony, hard substances that are in it. The palpation is usually done with right or left index finger.

Q. It is by touch, the sense of feeling?

A. That is right, the sense of feeling. It is like feeling a sack and trying to feel what is in it. That is exactly what you are doing.

Q. You take into your consideration size, also, do you not? A. Size, that is correct.

Q. If the size of the prostate is larger than usual, does that or does that not cause you to be suspicious of it?

A. If the prostate is larger than usual, we think of [570] something else, such as hyperthesis of the prostate gland.

Q. (By Mr. Danielson): The prostate gland is usually susceptible to carcinoma?

A. Yes, there is quite a lot of carcinoma of the prostate gland.

Q. Are you familiar with the normal incidence of carcinoma of the prostate?

A. Well, the figures vary on that. I am not sure of the figures.

Q. You have not conducted any clinical research into that? A. No, sir, I haven't.

Q. As to this blood test which was mentioned for carcinoma of the prostate, I believe that is also known as the acid phosphatase test or the acid alkaline phosphatase test? A. That is correct.

(Testimony of George E. Fakehany, M.D.)

Q. You have mentioned that you have never performed it yourself. A. I never have.

Q. And you are not personally aware of any doctors here who have performed it?

A. I am not sure, but I think Dr. Belt and possibly a couple of other leading urologists use that test.

Q. If Dr. Belt says he does use it——

A. I wouldn't frown on it. [571]

Q. You would not think it would be improbable, would you?

A. I wouldn't frown on it. That is right.

Q. I say, you would probably admit that that would be true, then? A. That is correct.

* * *

Q. (By Mr. Danielson): Now, Doctor, you have testified that you have no personal opinion as to whether the use of the hormone will accelerate the growth of an early or an incipient carcinoma of the prostate, is that correct?

A. Personally I don't know whether or not it will.

Q. You do not know whether or not it will?

A. That is right.

Q. Well, you are aware of the fact that there is at least a respectable portion of informed medical opinion holding that it will, is that not correct?

A. That is right, and there are quite a few say they don't know, and there are some that say it doesn't.

Q. But you are aware of the fact that there is a respectable portion saying that it will?

(Testimony of George E. Fakehany, M.D.)

A. I certainly am.

Q. Have you yourself done any clinical research or laboratory research into that particular subject? A. No. I have done none.

Q. None. Your opinion, then, would be based entirely on your study, reading and so forth?

A. Exactly.

Q. How many examinations of this type have you given, in your work?

A. Of course that varies. Not so many now.

Q. On an average, what is it, about 25?

A. During the war, it was about 25 a day.

Q. Is this examination a general physical examination, the standards of which are agreed upon by you and the employers, the companies?

A. Yes, it is.

Q. Such an examination would not necessarily include any special examinations, would it? Is it a routine established?

A. Well, that varies again with the organization. Some demand a very demanding examination. Some merely demand [573] an examination for hernia.

Q. But this standard is set up by the company, is that not correct?

A. That is right, they use the so-called general physical examination.

Q. As a matter of fact, if this company required one of these acid phosphatase tests, you would per-

(Testimony of George E. Fakehany, M.D.)

form it? A. I would not recommend it.

Q. If they demanded it, you would perform it?

A. Well, if they demanded it. I doubt if they would.

Q. Well, I am assuming if they demanded it, you would?

A. All right. If they did, I would, then certainly I would.

Q. Doctor, do you perform any surgery on the prostate? A. No, I don't.

Q. You have never removed a prostate, is that right?

A. No. I have assisted. The prostate glands are only removed by urologists.

Q. And you are not a urologist. I believe you testified to that.

A. I am not a urologist. That is correct.

Q. Do you frequently examine diseased prostates, I mean prostates for carcinoma?

A. Not frequently, carinoma of the prostate isn't frequently encountered in the normal private practice. [574]

Q. Then, you have not had a great deal experience with them, then, is that correct?

A. Well, I have had experience in the last 12 or 14 years, but not a great deal, no, I wouldn't say a great deal.

Q. Do you treat cancers of any kind?

A. I do. I treat cancers of any kind, anywhere where I may find them.

Q. Is it or is it not true that if a cancer is de-

(Testimony of George E. Fakehany, M.D.)

tected at an early stage, it is more susceptible to therapy? A. It certainly is.

Q. The smaller they can be found, the better they are? A. That is correct.

Q. Would you consider a cancer to be an early cancer if it is small enough so that it is susceptible to some beneficial therapy? [575]

* * *

The Witness: Yes, but it is a little ambiguous, frankly, because the size of a cancer does not necessarily determine the period of growth. In other words, you are presuming in your question that an early cancer is a small one. That doesn't necessarily follow.

Q. (By Mr. Danielson): No, some early cancers can be fairly large, then, is that correct?

A. That is right, and some late cancers can be small.

Q. In other words, the size of a cancer does not necessarily refer to its age?

A. That is correct.

Q. Although there could be some relation?

A. Generally speaking, there is a general relation, but it doesn't necessarily follow that an early cancer is a small one.

Q. Well, an early cancer could be as large as a grape, then?

A. Well, of course, "early" is a little ambiguous, too.

Q. Just on the basis that you just told us, couldn't an early cancer be as large as a grape?

(Testimony of George E. Fakehany, M.D.)

A. That is correct.

Q. Or even an acorn?

A. That is correct.

Q. Now, as to the subject of sterility, Doctor, you have testified that the use of the hormone, of testosterone, [576] would reduce the sperm count.

A. That is correct.

Q. But that you do not know whether it would cause sterility? A. That is correct.

Q. Is it not true, Doctor, that sterility or fertility is sort of a matter of relative sperm count?

A. That is correct. That is correct.

Q. If the sperm count is reduced below some figure, I believe it is about 150,000,000——

A. Yes, I think that is it.

Q. Then, you are considered clinically sterile, but above that clinically fertile, is that correct?

A. That is correct.

Q. Do you not believe, Doctor, that it is possible with the prolonged use of testosterone to reduce this sperm count below 150,000,000?

A. Yes, I think that the use of testosterone will reduce the sperm count, but I doubt if it will reduce it sufficiently, enough to produce sterility.

Q. Below 150,000,000?

A. Well, I don't know. It is hard for me to answer that. I have never done a sperm count on these patients.

Q. I see.

A. I am testifying from what I have read in the literature. [577]

(Testimony of George E. Fakehany, M.D.)

Q. You have not conducted any independent research? A. That is correct.

Q. Into the subject of sterility?

A. That is correct.

Q. Or on the subject of the effect of testosterone on fertility or sterility?

A. That is correct. As far as my personal experience is concerned, I have never had any adverse results in that way, I have never seen it make any of my patients sterile.

Q. Now, I want to ask you a question there, Doctor, in considering a patient who, let us say, wants testosterone and you know of no immediate pathological condition which would contra-indicate testosterone, but in view of the indefinite knowledge as to what effect this will have on sterility and yet knowing that it will reduce the sperm count, would you recommend testosterone to a man who wished to procreate, to whom fertility was important?

A. No, I don't believe I would.

Q. Now, you testified that the male sex hormones at least has some value in cases of male hormone deficiency? A. It appears to have.

Q. Do you have any opinion as to whether a lay person can determine whether he has a hormone deficiency?

A. Well, he may have an idea that he has. [578]

Q. But as to whether he can diagnose it?

A. I don't think he could diagnose it.

Q. As a matter of fact, diagnosing of a male sex

(Testimony of George E. Fakehany, M.D.)

hormone deficiency is a rather difficult examination, isn't it? A. Well——

Q. Have you not testified, Doctor, that under certain symptoms that a person may have different deficiencies and then I believe, to use your words, by the use of trial and error you determine whether or not the hormone is beneficial?

A. That is correct.

Q. And is not the reason for that that the determination of whether or not a person has this deficiency is oftentimes very difficult?

A. I did not understand the last.

Q. To go in the back door on this——

A. All right.

Mr. Danielson: We will agree, I presume, that a castrate has a male hormone deficiency.

The Witness: That is correct.

Q. And likewise, a hypogonad has male hormone deficiency? A. Correct.

Q. Now, take a person who is apparently normal, who apparently possesses all of his organs, the doctor, to determine whether or not there is such a deficiency, takes what [579] steps, what steps must be taken, how would you determine it with such a person? A. In a hypogonad?

Q. No. In a person who is apparently normal in his physical makeup.

A. Well, there is actually no way of determining exactly whether or not he has. You must listen to the patient's story and try to evaluate the symptoms that he presents and if his symptoms fall into a cer-

(Testimony of George E. Fakehany, M.D.)

tain category, we merely presume that he has a male hormone deficiency.

Q. And that is when this so-called trial and error procedure comes into play?

A. That is correct.

Q. But prior to that, though, would you not try to determine whether or not a man has a cancer of the prostate?

A. I would not necessarily look for a cancer of the prostate. I would talk to the patient and actually, if he had any symptoms that suggested prior cancer of the prostate, I certainly would investigate.

Q. And how do you determine those symptoms, by the use of what method? That is by rectal examination? A. Palpation, correct.

Q. And if you found any suggestion of carcinoma of the prostate, would you then recommend testosterone or prescribe it? [580]

A. I don't think I would. I would respect the literature that I read.

Q. Is it correct, Doctor, then, the use of a male hormone or any hormone, for that matter, should be what is known as a replacement therapy?

A. That is correct.

Q. To replace that which Nature no longer provides, at least not in adequate quantities?

A. That is correct. [581]

Q. As to these symptoms that were mentioned by Mr. Elson, the flushes, sweats, nervousness, irritability and nocturia and so forth, isn't it a fact

(Testimony of George E. Fakehany, M.D.)

they are also the results of something besides hormone deficiency?

A. Any one of those symptoms may be present in anyone or may indicate another disorder. However, that confusion is usually seen in the so-called male climacteric.

Q. How about in anxiety states?

A. An anxiety state might present any symptom or combination of symptoms.

* * *

Q. (By Mr. Danielson): Are not those symptoms of exophthalmic goiter?

A. Some of them are.

Q. How about fatigue states? [582]

A. A fatigue state is one.

Q. And fatigue is rather common in the present day and age, isn't it? A. Yes.

Q. How about tuberculosis?

A. That is a common symptom of tuberculosis.

* * *

Q. In your testimony as to your examination of your patients, Doctor, you mentioned that you talked to them a few minutes. I gathered that you meant by that that you were taking their history? [583] A. Yes, sir; that is correct.

Q. And your purpose is to benefit your patients, when you speak of trial and error. You do not by that mean that you do not attempt to make an accurate diagnosis? A. Certainly not.

Q. I just wanted to make that clear. Your atten-

(Testimony of George E. Fakehany, M.D.)

tion was directed on direct examination to the testimony of Dr. Huggins to the effect that certain experiments were conducted in some cases in hospitals in which he was employed.

A. Yes; I heard that.

Q. That is a usual procedure, is it not, insofar as you know?

A. Do you mean to conduct these experiments?

Q. To talk about their history is not the sort of thing you were referring to by trial and error, is it?

A. That is correct; it is not.

Q. There are, obviously, fields in medical science which are not yet known?

A. That is true, and certain medicines are prescribed in order to try to obtain the best results.

Q. And that is for the purpose of determining what is the therapeutic effect of those medicines?

A. That is correct. That is common.

Q. In regard to estrogens, the female sex hormones, have you ever conducted any clinical or laboratory research into [584] that field? A. No.

Q. Your statements and opinions, then, are based on your reading, study and possibly discussions with other doctors? A. Correct.

Q. And that would include, then, your lack of clinical experiment and would include or would, likewise, apply to any experiments in connection with the female genitalia or the male genitalia?

A. Yes; that is correct.

Q. As to impotence, I believe you stated that impotence is frequently of psychogenic origin?

(Testimony of George E. Fakehany, M.D.)

A. I did.

Q. And, likewise, you felt that, when you gave the male hormone, you sometimes had some alleviation of the impotence?

A. At least, the patients have had it.

Q. You say the patients have told you they did have a benefit? A. That is correct.

Q. Is it not true, Doctor, that in cases of psychogenic origin, any type of treatment in which the patient has faith will sometimes produce a beneficial result? A. That is true of any disorder.

Q. Isn't that true of the old-fashioned sugar pill that [585] was given years ago?

A. It is true that the sugar pill will benefit patients.

Q. Are you not aware of the fact that among lay people at least there is some belief that oysters as such have a beneficial effect on people?

A. Yes; you will hear that.

Q. And such effects are not directly traceable to testosterone?

A. We try to differentiate. We try to determine whether or not the results are actual results or whether they are those of a psychogenic patient merely stating he got results. I think every doctor tries to determine those.

Q. As to the testimony relative to the destruction of the semeniferous tubules, do I understand that you do not know how such would be determined?

A. That is correct, in man.

(Testimony of George E. Fakehany, M.D.)

Q. How about a biopsy? Would that not determine it?

A. Well, you would have to take a biopsy before and one after.

Q. If there were a pre-treatment biopsy and a post-treatment biopsy, that could be determined?

A. I would say it could.

Q. Are you familiar at all with the work of Dr. Warren O. Nelson, of the University of Iowa, clinically? A. No; I am not. [586]

Q. However, if you were to hear him testify that he has performed such experiments, you would not doubt them for that reason alone?

A. No; I certainly would listen to them eagerly.

Q. As to determining whether there is such a thing as a male sex hormone deficiency, your attention was directed to the testimony of Dr. Heckel, who said, on page 176, "Q. Now, Doctor, how is male hormone deficiency in any person determined?

"A. Determined by, first, a careful history——"

You have no disagreement with that, have you?

A. No.

Q. "No. 2, a careful physical examination——"

Q. You do not disagree with that, do you?

A. No.

Q. "And No. 3, there are some laboratory tests that will aid in diagnosis, such as the estimation of 17 ketosteroids in the urine."

You have no disagreement with that, Doctor, have you? A. No; I haven't.

Q. You are familiar, I am confident, with the physiology of the testes? A. Yes, sir; I am.

(Testimony of George E. Fakehany, M.D.)

Q. And that the sperm are produced in a different part of the organ than the testosterone is produced? [587] A. That is right.

Q. Would it not be possible by a biopsy examination to determine whether the testes are still able to produce testosterone?

A. Under controlled laboratory conditions, they can, with biopsy, determine the sperm count and the shape and configuration of the sperm, but I don't think they can isolate the testosterone.

Q. No, I say by a biopsy of the testicle to determine whether the interstitial cells are still in a normal state.

A. I think they can determine quite a bit.

Q. If you heard testimony of a doctor who said he had devoted about 10 to 15 years to such research and was able to determine that, would you have any reason to doubt it?

A. I wouldn't doubt him but I wouldn't necessarily accept him, either.

Q. You have never performed any such research yourself? A. I have not.

Q. Is it not true, Doctor, that there is no necessary connection between impotence on the one hand and sterility on the other? A. That is right.

Q. The fact that a man is impotent doesn't necessarily mean that he is sterile? [588]

A. That is correct.

Q. And vice versa? A. That is correct.

Q. You gave an opinion, Doctor, as to whether 5 milligrams per day of alpha estradiol would have any effect——

* * *

(Testimony of George E. Fakehany, M.D.)

Q. (By Mr. Danielson): Excuse me; as to whether 5/10 of a milligram per day of alpha estradiol would have any effect upon a female. Have you conducted any experiments to determine that point?

A. I haven't conducted any experiments.

Q. You have administered different dosages of the female hormones? A. I have.

Q. Is it not true that you found that the therapeutic effect of the hormone varies in different people? A. It does.

Q. That is, some people seem to respond more quickly or easily than others? A. Correct.

Q. A small amount has as much effect on one person as a large amount may have on another person? A. Correct.

Q. As to the kind of hormone dosules which I believe [589] you said you have used, I believe you stated that your results have been ambiguous but that some of the patients said they thought they noticed some beneficial results? A. Yes, sir.

Q. Was that for cosmetic purposes, to develop the bust?

A. Yes; that is what it is commonly used for.

Q. You mentioned that some of your patients stated that, in their opinion, there was some benefit. Did you ever see any benefit, in your own opinion, from the use of this Menformon Dosule?

A. The patients don't usually continue it long enough for a doctor to actually take a look at a woman's bust and determine whether it has been

(Testimony of George E. Fakehany, M.D.)

enlarged or not. In other words, if there was an enlargement—after all, we don't measure a woman's bust when she comes into the office. We must take her word for that sort of thing, the size of it.

Q. In the cases you have cited, have you ever seen this cosmetic effect?

A. No; I can't say I have.

Q. As to the use of hormone by yourself, may I ask you how long a therapy you have taken over one period of time?

A. Oh, I have taken them two or three weeks at a time.

Q. Would that be a tablet per day?

A. About two tablets per day.

Q. Doctor, if you had any suspicion at all that you had [590] an early or incipient carcinoma of the prostate, would you have done that, this is, taken that treatment?

A. I doubt if I would because the mere fact that someone else suggests it might have some bad effect or do some injury would be enough for me not to try it.

Q. Would you consider that good professional practice at least? A. I would say so.

Q. As to the use of alpha estradiol in females in which there is uterine bleeding, isn't that bleeding at least one symptom of a cancer of the genitalia?

A. It is.

Q. And, under those circumstances, you would immediately stop the use of that drug, would you not? A. I would.

(Testimony of George E. Fakehany, M.D.)

Q. As to the male climacteric—you stated that in the female there are definite findings in case of the climacteric? A. Correct.

Q. That would be a cessation of ovulation, for one thing?

A. That wouldn't be a finding clinically speaking. Clinically speaking, it is a cessation or stop of the menses.

Q. Something happens to the ovary at that time, doesn't it? [591]

A. Yes; they shrink up.

Q. And they cease producing hormones, do they not? A. That is right.

Q. Now in comparable cases in men, if there were a male climacteric, what would be the finding or phenomena in the male?

A. We presume that the testes would shrink up.

Q. And would no longer produce sperm?

A. No longer produce testosterone.

Q. How about the sperm?

A. The sperm count is diminished.

Q. In the female the ovary would no longer produce its eggs? A. No, sir.

Q. As a matter of fact, you have conducted sperm counts at least in college? A. Oh, yes.

Q. Is it not true that in men of advanced years there is frequently a substantial sperm count?

A. Yes; there might be.

Q. Have you ever conducted any such tests?

A. Well, frankly, I don't recall conducting them

(Testimony of George E. Fakehany, M.D.)

in any elderly gentlemen but I know for a fact that some of them do have a good sperm count.

Q. You have never made any study of that particular [592] subject? A. No; I haven't.

Mr. Danielson: No further questions.

Mr. Elson: I just have one or two questions.

Redirect Examination

By Mr. Elson:

Q. Mr. Danielson asked you if fatigue and so on wasn't usually associated with a certain type of goiter and tuberculosis.

Mr. Danielson: That is a misinterpretation. I will straighten it out, if you wish. At that point I was referring to the symptoms which have been frequently mentioned and are contained——

Mr. Elson: Yes, nervousness and so on. I think you stated that they were associated with a certain type of goiter and with tuberculosis.

Mr. Danielson: That is correct, those same symptoms.

Is that not correct, Doctor?

The Witness: No. You were referring to the symptom of fatigue.

Mr. Danielson: Then, I wish to correct it for that wasn't my intention. I referred to nervousness and irritability.

The Witness: No; not all of them would be symptoms of those diseases. I told you some of them might be and you asked me about fatigue and

(Testimony of George E. Fakehany, M.D.)

I told you fatigue would be a [593] symptom, too, of tuberculosis and exophthalmic goiter.

Mr. Danielson: I am interested in the symptoms which are reflected in Government's Exhibit 1, flushes, sweats, chills, lack of sexual power, impaired memory, inability to concentrate on activities or tendency to evade them, nervousness, depression, general weakness and poor physical strength. Are not those symptoms likewise the symptoms of a state of fatigue?

The Witness: I would say that some of them were but not all of them.

Mr. Danielson: Some of them are?

The Witness: That is correct.

Mr. Danielson: And, likewise, some of them are of tuberculosis?

The Witness: Correct.

Mr. Danielson: And some of them are of this goiter I referred to?

The Witness: That is right.

Mr. Danielson: That is all.

Q. (By Mr. Elson): How many men in your practice that have come to you complaining of these symptoms, for whom you prescribed testosterone, had goiter or tuberculosis?

A. Frankly, I can't recall any that did have.

Q. As a matter of fact, if they did, you would have adopted a different mode of treatment, wouldn't you? [594]

A. They are quite easily detected.

Mr. Elson: That is all.

(Testimony of George E. Fakehany, M.D.)

Recross-Examination

By Mr. Danielson:

Q. About how many of them had fatigue, Doctor? A. Quite a few of them.

Mr. Danielson: Thank you. That is all.

The Court: Do you prescribe the drug testosterone for loss of memory or failure of memory?

The Witness: In a man past 55, I would say yes. With no other obvious cause for that symptom, I would.

The Court: I have no other questions.

Mr. Elson: I have no further questions. [595]

* * *

Mr. Elson: Your Honor, the clerk tells me that the record does not show Defendants' Exhibit B for identification to be in evidence. That is a report of the State Board of Pharmacy we discussed this morning. So that now I offer Defendants' Exhibit B for identification into evidence.

The Court: It is in evidence.

The Clerk: Defendants' B in evidence.

(The document referred to was marked Defendants' Exhibit B and received in evidence.)

Mr. Elson: Dr. Paul Travis.

DR. PAUL EDWARD TRAVIS, M.D.

called as a witness by and on behalf of the defendants, having been first duly sworn, was examined and testified as follows:

The Clerk: Your full name?

A. Paul Edward Travis.

Direct Examination

By Mr. Elson:

Q. Doctor, are you a medical doctor?

A. Yes, sir.

Q. And you have an M.D. degree?

A. That is right.

Q. Will you please state the schools that you went to? [596]

A. Undergraduate, University of Southern California, A.B. degree in 1941, University of Iowa——

Q. Just a minute. In connection with your A.B. degree, was there any particular honor conferred upon you?

A. I was a member of Phi Beta Kappa, University of Iowa, 1942, Master's degree in physiology, and then back to the University of Southern California for a medical degree in 1946, interned at the Santa Fe Hospital for 12 months and then at the request of the government, spent two years in the service, stationed at the Veterans' Hospital in Phoenix, Arizona, and returned to private practice in 1948.

Q. All right. Now, have you ever used a product known as testosterone, in your practice?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes, sir, I have.

Q. In your private practice? A. Yes.

Q. Did you use it while you were at the Veterans' Hospital?

A. Yes. We used it there, also.

Q. Now, are you familiar with the term known as the male climacteric? A. Yes.

Q. What do you associate with that term in connection with the symptoms of a male?

A. Well, it is the change of life in a man, and—— [597]

Q. And what usually from your experience have you found to be the symptoms that are associated with it?

A. About the same as with the female.

Q. And what would those be?

A. And that is a loss of libido.

Q. Libido, for the record, is what?

A. Well, libido is sexual drive; loss of libido, a feeling of a sense of not well being, the patient doesn't feel well, usually they are nervous, irritable, they have insomnia, they are not able to sleep well at night. They just come in and say, "Doc, I don't feel well."

Q. Now, then, have you had patients of middle life, male patients of middle life, come in to you and complain of some of those symptoms?

A. Oh, yes.

Q. And have you on such occasions, not on all but on some of those occasions, prescribed testosterone to them? A. Yes.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. And did you afterwards see those patients, some of them? A. They came in, yes.

Q. And with some of those patients did you find that the symptoms appeared to be relieved?

A. Very definitely.

Q. Now, you know what I mean when I speak of hypogonadism? [598] A. Yes.

Q. A person who is a hypogonad, who is suffering from a male hormone deficiency?

A. Not necessarily. There are several hormones tied up in hypogonadism.

Q. Well, we will say that if a person's scrotum was not the normal size of a person of his age, his penis was not of the normal size of a person of his age, he did not have the distribution of body hair that would be associated with the normal individual of his age, his muscular development was not that of a person of his age and his voice was a high-pitched voice, in your opinion, would the male sex hormone testosterone be of any aid to that person?

A. Oh, yes, along with other products.

Q. Now, assuming that a person is lacking in male hormone deficiency, he has a male hormone deficiency and complains of a lack of sexual power and impotence, in your opinion would testosterone be of assistance to that individual in overcoming it?

A. Definitely.

Q. People suffering from male hormone deficiency, has it been your experience that testosterone improves their physical and mental work?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Oh, very definitely, yes. [599]

Q. Does it appear to impart a renewed vigor to the individual? A. Yes.

Mr. Danielson: Your Honor, I object to this. I suggest that counsel ask the witness what the drug does rather than tell the witness what the drug will do. It is a little bit too leading, I believe, your Honor.

Mr. Elson: All right.

Q. You have mentioned some of the symptoms that are associated with this deficiency other than those that you have testified to. Can you at the moment think of any others?

A. Well, it definitely gives them a better night's rest, many of them gain weight on testosterone, males who have been losing weight, and it seems to increase their appetite and impart a general sense of well-being and they are a little bit better able to concentrate, and such things like that.

Q. Now, when a person comes to you and complains of symptoms such as we have mentioned, what do you ordinarily do, what would you do with such an individual, starting at the commencement?

A. Try him out on the drug and if it helped him, that certainly would be the answer.

Q. And what would be the length of time that you would expect the man to have some relief, if he was suffering from such a deficiency? [600]

A. You mean the length of time that it would take to obtain relief?

Q. Yes.

(Testimony of Dr. Paul Edward Travis, M.D.)

A. We usually see relief in two to three weeks, upon the usual dosage.

Q. Now, page 39.

The Court: What are your usual doses?

The Witness: I beg your pardon, sir?

The Court: What are your usual doses?

A. We give them, according to the weight of the patient, 25 to 50 milligrams of testosterone a day.

Q. (By Mr. Elson): That would be in tablet form? A. Yes, the methyl testosterone.

Q. Now, the other day, a Dr. Thienes testified for the prosecution as to what in his opinion the general practitioner would do with a man in middle life who complained of some of these symptoms, prior to prescribing testosterone, and I am going to call your attention to pages 39 to 41. This is not verbatim from the transcript, but it is a digest of it. I think you will find it correct.

Assuming a man to be 50 years of age who complains of flushes, sweats, extreme nervousness, inability to concentrate, nocturia, and he goes to his doctor who is an average general practitioner, and no evidence of cancer of the prostate has been diagnosed, Dr. Thienes says that he does not [601] believe that the doctor would prescribe testosterone for a period of time and wait to see whether the symptoms were relieved. Before he would answer that the general practitioner would prescribe it, he would have to know more about what his general examination consisted of, what the urologist had done by way of examination, if the urologist's re-

(Testimony of Dr. Paul Edward Travis, M.D.)

port was that he had palpated the prostate and performed a biopsy and found no evidence of cancer of the prostate and no enlargement of the prostate, and laboratory tests showed that there was a decrease in the secretion of testosterone, even then in his opinion testosterone would not be prescribed by the man's doctor unless there was further evidence of the male climacteric.

Now, is it your practice to follow the route that was testified to by Dr. Thienes before prescribing it under those conditions?

A. No. A general practitioner doesn't have the time nor does his patient usually have the funds to undergo such an expensive laboratory determination, and I never do it.

Q. Do you know of any other practitioners that follow such a routine?

A. Not if they are a busy practitioner.

Q. In the practice of medicine, is it common or uncommon for you, when a person comes in and complains of certain things, to diagnose it to the best of your ability and arrive [602] at what you think will relieve him and then, if that does not work, try something else?

A. Yes, that is the practice of medicine.

Q. And in the practice of medicine, isn't it largely a matter of trial and error?

A. That is all you have got to go by in most instances.

Q. Now, when you were with the Veterans' Ad-

(Testimony of Dr. Paul Edward Travis, M.D.)

ministration Hospital, I think you stated that you gave testosterone? A. Yes.

Q. Will you state the circumstances under which you gave it and how it was given?

A. Well, usually the patients were hospitalized and most of our veterans that were given testosterone were past middle age, with a concomitant physical ailment such as asthma, or bronchiectasis, or a heart condition, whom we felt would give them the added energy perhaps to make ambulatory roll call each morning, because most of them just like to lie around in bed, and by giving them testosterone, it seemed to give them enough energy and a little more libido to be ambulatory so as to go to ambulatory mess, and gave them a sense of well-being and took their minds off their own ailments and made them a little more cheerful.

Q. Did you give any examinations to these patients before giving them this testosterone?

A. We gave just a general physical. [603]

Q. And what does a general physical embrace?

A. Why, eye, ear, nose and throat examination, heart, lungs, abdomen, prostatic examination. That is about all.

Q. By the way, about how long does it take to make a prostatic rectal examination, ordinarily.

A. About 30 seconds.

Q. In your experience have you ever encountered any adverse results from the administration of testosterone? A. No, sir, I haven't.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Enlargement of the prostate, as a rule, is that a cancerous condition or something else?

A. As a rule, it is not a cancerous condition.

Q. What is it?

A. Well, doctors like to abbreviate things, they call it prostatic hypertrophy. It is simply a benign enlargement of the prostate. That is the most common cause of the enlargement of the prostate.

Q. The other day, one of the government witnesses, Dr. Heckel (page 173) stated that in his opinion males of middle age do not suffer from a deficiency of the male hormone. Do you agree with that statement? A. No, I do not.

Q. Have you in your experience found the contrary? A. Yes. [604]

Q. Now, also Dr. Heckel stated that a male hormone deficiency in any person prior to the prescription of testosterone is determined, 1, by a careful history; 2, by a careful physical examination, and 3, by laboratory tests, such as an estimation of 17 ketosteroids in the urine. Do you follow that examination in determining whether or not a person is suffering from a deficiency prior to the prescription of testosterone?

A. No, because, as I stated before, this has to do with a specialist's laboratory, laboratory tests. I don't do them in my office. I don't have the facilities. I doubt whether the average clinical laboratory in the outlying districts would be capable of doing a 17 ketosteroid.

Q. Is that an established or a rare test?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. It is a rare test.

Q. Do you know of any doctors that run that test prior to prescribing testosterone?

A. Not in my section of town. Perhaps an urologist but not of my knowledge.

Q. This same Doctor Heckel, when asked how cancer of the prostate was diagnosed, answered, at page 182, in substance, as follows, that in the majority of men the diagnosis is by rectal examination, but that in early stages, however, of prostatic cancer it may be necessary to supplement the rectal examination with a biopsy, as there are two other conditions [605] that may simulate an early prostatic cancer; that one is a stone in the prostate and the other is an area of inflammation. In your practice, have you ever performed a biopsy upon a person's prostate to determine whether or not it was cancerous?

A. No; I never have but I have referred patients to an urologist if I suspected he might have cancer of the prostate.

Q. That is after you definitely suspected it on diagnosis that you have made yourself?

A. Yes, sir; that is right.

Q. Is it usual practice, from your experience, for doctors in this locality to perform a biopsy upon a patient's prostate after they have not been able to find it by a rectal examination?

A. I don't think any general practitioner would undertake to do anything like that.

Q. Why?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. For one thing, it requires special instruments, for instance, a cystoscope, and I don't think any general practitioner owns one. Consequently, there are complications from a biopsy which a general practitioner is not prepared to meet. One is bleeding. The prostate is a very vascular organ and after biopsy it is necessary to coagulate the area there in which you take the biopsy. This all, very definitely, is a [606] specialist's technique, and it is a thing I would not be capable of performing myself. I imagine an urologist would be the man to do that, although I don't know whether they do that in their offices or not. It sounds more like a hospital procedure.

Q. From your experience with patients, what do you think a patient's attitude would be towards such a suggestion?

A. He would probably never come back if you suggested it.

Q. In this complaint it is charged that testosterone, 25 milligrams per day or 50 milligrams per day of methyl testosterone, may accelerate the growth of an incipient cancer of the prostate or may cause sterility. From your experience, do you believe it is possible for you to diagnose an incipient cancer of the prostate?

A. I don't know of anyone who can diagnose an incipient cancer.

Q. Will you state why?

A. "Incipient" means at its very beginning or in its early stage, and it is a very difficult thing to

(Testimony of Dr. Paul Edward Travis, M.D.)

contact. Any disease in its incipient form is practically undiagnosable or undetectable.

Q. How large would you think a cancer of the prostate would have to be before you could locate it by palpation? [607]

A. It has to involve one of the lobes before it could be detected. That is about a quarter of the prostate.

Q. Dr. Heckel the other day, starting at page 186, stated, as to a patient coming to a general practitioner, that, in his opinion, the first thing he should do is to make a careful examination of the patient to see if he can find out what is producing the symptoms; that he would make a complete physical examination from head to foot, and, if that produced nothing, he would probably examine the urine to see whether there was any sugar in it, which might give him a clue to diabetes which would produce this sort of symptoms; that, if he assumed there was no sugar, he would then look at the urine to see whether there was albumin in the urine or casts in the urine, which would indicate that the patient, in all probability, would be suffering from Bright's Disease or some kidney disturbance; that then, if nothing turned up, he would take the patient's blood pressure and, if that was normal and his urine negative, he would probably take a blood count to see whether the patient was suffering from anemia or had some blood disturbance; that there might be some indication that the patient had a gastro-intestinal disturbance and an X-ray picture

(Testimony of Dr. Paul Edward Travis, M.D.)

of the stomach or an X-ray picture of the colon should be taken or a basal metabolic test made to discover whether or not he had some disturbance of his thyroid; that such a doctor wouldn't [608] suggest testosterone to the patient to be tried for a period of say four to six weeks and see if those symptoms were relieved, that is, that he might but he shouldn't. In your practice, do you follow the method that has been outlined by Dr. Heckel as a condition precedent to the administration of testosterone?

A. I don't think any general practitioner could afford to go through that rigmarole on any patient before giving such a simple medicine as testosterone.

Q. Do you know of any doctors who do so?

A. No; I don't. A general patient coming in for a little relief of some fatigue, nervousness and so forth, is not prepared to meet a laboratory examination fee of upwards of $50 for a blood count and so forth. That is shotgun laboratory diagnosis and I don't think any ordinary patient can afford that sort of treatment.

Q. Have you read any of the literature concerning testosterone and its relationship to growth of cancer of the prostate?

A. There are articles pro and con on the subject; yes.

Q. What do you mean by pro and con?

A. Some say that testosterone will accelerate growth of a cancer of the prostate and some say it

(Testimony of Dr. Paul Edward Travis, M.D.)

has no effect and others definitely state it inhibits the growth of cancer of the prostate. [609]

Q. Based on what you have read and from your experience, do you consider testosterone to be dangerous? A. Absolutely not.

Q. In connection with the subject of sterility, taking the same man, we will say, who comes to you and complains of nervousness, fatigue and so on, as we have discussed, from your experience is the question of sterility or fertility of importance to such a man as compared to being relieved of his symptoms?

A. Certainly not; especially if he is 45 years or over. He has had his family and, if he has not, it is too late anyway.

Q. Is it usual for you to discuss the subject of sterility or fertility with such an individual before prescribing for him?

A. Sometimes, but what they are interested in is their symptoms, not procreation at the age of 45, 50 or 55.

Q. In connection with your practice, you receive considerable literature, do you from the various manufacturers of testosterone, from Ciba, Roche-Organon and Schering?

A. Yes; we get a lot of literature on various drugs daily.

Q. Do you consider that the information contained in that literature is authentic?

A. Absolutely. [610]

Q. It is, so far as you know, the practice of

(Testimony of Dr. Paul Edward Travis, M.D.)

other doctors that you know of to rely upon the literature that is thus furnished to them?

A. As to the general practitioner, that is one of his main sources of current information, the literature from the drug houses.

Q. And that is furnished by what we know as the detail man, is it not?

A. The detail man and then they send it to you through the mail.

Q. We have talked about detail men here. Will you explain to the court what a detail man is?

A. He is a representative from the various drug houses and he calls upon you, the doctor, and brings samples of their various medical products and literature pertaining to those samples, and he tells you how they were developed, what they are used for, their price, and he gives you information regarding the drug. Whether it be new or old or whatever type of drug it is, it is explained to the general practitioner.

Q. On the same subject of sterility, have you in your experience ever found the administration of testosterone to make a man sterile?

A. I don't think I have ever examined for sterility because a man complaining of symptoms referable to the male climacteric has usually passed the age of fertility, and [611] they are not interested in that and never inquire about it. They never come to the doctor and say, "I can't have a child. Why not?" At 45 or 50 they are not interested in that.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Do these symptoms you speak of appear to the individual to be really distressing?

A. Absolutely.

Q. Have you examined or read any of the literature on the subject of testosterone and its relation to sterility?

A. Again, that is very controversial——

Mr. Danielson: Just a minute. Will you answer the question directly in this particular case?

The Witness: Yes; I have read it. You get a lot of it.

Q. (By Mr. Elson): Go ahead.

A. But this is controversial.

Q. By that you mean what?

A. Some say it produces sterility. Other doctors claim that it has no effect on fertility, and other doctors even seem to think that it will relieve sterility.

Q. Coming to the subject of estrogen, alpha estradiol, are you familiar with that substance or drug? A. Yes, sir.

Q. In connection with your work, do you use a book called "Physician's Desk Reference, 1948"?

A. I have that on my desk; yes. [612]

Q. Just what is that?

A. Well, it is put out, or I believe it is put out, by the Year Book people. I am not sure about that now. But it is a general therapeutic index to practically all drugs manufactured in one certain year. You can find anything there from aspirin right on

(Testimony of Dr. Paul Edward Travis, M.D.)

up to penicillin. It includes all of the drugs that are manufactured.

Q. Did you look at that work before you came up here to court? A. Yes. I have it on my desk.

Q. And did you look at it with reference to alpha estradiol?

A. I knew that was going to come up. So I did; yes. [613]

* * *

Q. (By Mr. Elson): Coming to a half a milligram tablet of alpha estradiol, a dosage of two per day, in your opinion, would that dosage be dangerous to a female in that it might accelerate a cancer of the breast, cervix or uterus?

A. No, because we don't know that estrogen will stimulate a cancer of the breast, cervix or uterus.

Q. What do you mean when you say "we don't know it"?

A. I don't think it is even definitely proved.

Q. Is there an opinion that it may and an opinion the other way that it may not?

A. Absolutely. Like in any phase of medicine, there are always two opinions.

Q. Have you encountered any adverse results in patients who took alpha estradiol?

A. I had one patient who thought that, if two tablets per day did her good, she would take four and she produced uterine bleeding inside of three weeks. Upon cessation of the drug, the bleeding stopped.

Q. On that subject of uterine bleeding, do you

(Testimony of Dr. Paul Edward Travis, M.D.)
think, if a woman took enough alpha estradiol to cause uterine bleeding, that that would be dangerous to the woman?

A. No. It would simply indicate that she was taking too much and she should stop. [614]

Q. Has it been your experience that usually, when women start uterine bleeding, they come to the doctor anyway?

A. Absolutely. That brings them back in a rush.

Q. Dr. Macdonald stated here—do you know Dr. Macdonald?

A. Yes. He was a former professor of mine in the University of Southern California.

Q. Dr. Macdonald stated, in his opinion, such dosage might produce acceleration of the growth of a cancer and so on, and the danger that he associated with it, page 130, was, as a result of this bleeding—he said it is difficult to tell whether such bleeding is a result of the developing growth, malignant or otherwise, in the uterus, or whether it is simply due to a disturbance of the lining of the uterus, from the use of the hormone. Now, under such circumstances, do you consider that dangerous?

A. No. As a matter of fact, it is beneficial. If a patient comes in to you with uterine bleeding and if it doesn't cease, that is, if they are taking estrogen. if it doesn't cease upon removal, then you are definitely suspicious and maybe you do a curettement to see what is causing the bleeding. I think it is beneficial for the patient to come in.

(Testimony of Dr. Paul Edward Travis, M.D.)

Mr. Danielson: What is this thing you are going to do? [615]

The Witness: A curettement, which is a scraping of the lining of the womb to determine whether there is an over-development of the lining of the womb or whether there is cancer there.

Q. (By Mr. Elson): Doctor, coming to a tablet of alpha estradiol of .1 milligrams per tablet per day for a period of 10 days and thereafter one per day, in your opinion, would the taking of such a dosage of that quantity be dangerous to the individual? A. No.

Q. Do you consider that to be a large dose or a small dose?

A. It is a moderate dose. It is not small and it is not large.

Q. You are familiar with the dosules used for breast development, are you?

A. Do you mean creams, estrogen creams?

Q. Estrogen creams or something. A. Yes.

Q. With reference to count 3, Government's Exhibit 3, Menformon Dosules, I show you now the exhibit, consisting of the labeling, and ask you to read it. A. Yes.

Q. Doctor, have you ever used that product or a similar product, of similar strength? [616]

A. Yes, I have.

Q. And with what results?

A. I had excellent results in one case. In a couple of others they said they got good results but in one case it very definitely had a marked increase

(Testimony of Dr. Paul Edward Travis, M.D.)
in the size of the bust, following the administration for about three months.

Q. Is it unusual in the practice of medicine for a drug to be efficacious or appear to have therapeutic value with one person and not have it with another? A. That is the rule; yes.

Q. Have you read any of the literature on the use of such dosules?

A. Yes. The French are great on that medicine. As a matter of fact, I think they originated the work and had the original cream, and they are very keen on it and have reported numerous articles in which they have gotten excellent results. I think probably they are a little biased in reporting such a high percentage of results but I do think you can get results with a properly selected case.

Mr. Elson: You may cross-examine.

Cross-Examination

By Mr. Danielson:

Q. Doctor, I believe you testified you are now practicing medicine here in Los Angeles?

A. A general practitioner; yes.

Q. In private practice? [617]

A. Yes, sir.

Q. How long have you been so practicing, Doctor?

A. Since July 1, 1948.

Q. Roughly, one year? A. Roughly.

Q. Prior to that time you were with the Veteran's Administration?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes; for two years.

Q. And prior to that you were an interne, is that correct? A. That is right.

Q. And you have had one year of general practice so far? A. That is right.

Q. Are you an urologist, Doctor?

A. Not as a specialist; no.

Q. In other words, you don't specialize in urology? A. Oh, no.

Q. Are you an endocrinologist, Doctor?

A. No; not as a specialist.

Q. Are you a gynecologist? A. No, sir.

Q. In other words, you are in the general practice? A. Everything from toenails to hair.

Q. What is your professional address? [618]

A. Huntington Park.

Q. I mean your office address?

A. 7310 Seville Avenue in Huntington Park.

Q. California? A. California.

Q. Are you acquainted, Doctor, with a doctor by the name of Charles Huggins, or with his work?

A. Yes; we studied that in medical school.

Q. Do you consider him to be an authority in his field, Doctor? A. Yes; he is.

Q. Are you acquainted personally or by reputation with Dr. Elmer Belt of Los Angeles?

A. By reputation.

Q. Do you consider him to be an authority in this field? A. Oh, yes.

Q. Are you personally acquainted with or by reputation with Dr. Norris J. Heckel?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. No; I don't know him.

Q. Or Dr. Ian Macdonald in Los Angeles?

A. He was a professor of mine.

Q. Do you consider him to be an authority in his particular field? A. Yes. [619]

Q. In fact, he taught you a good deal of what you know, I presume? A. He surely did.

Q. Are you acquainted at all with Dr. Warren O. Nelson? A. No; I am not.

Q. Of the University of Iowa?

A. I don't happen to be.

Q. You attended the University of Iowa, did you not? A. Yes, but in another department.

Q. How old are you, Doctor? A. 28.

Q. You spoke of the male change of life or male menopause or climacteric and in so doing you mentioned that the symptoms would be comparable to the symptoms of the climacteric or menopause in the female.

A. Except for cessation of menses; yes.

Q. Just what are the primary findings or the phenomena associated with the change of life in a female? Are they not a cessation of ovulation?

A. We assume that to be the case; yes. We can't tell but we know that to be true because the menses cease.

Q. And with that an atrophy or shriveling or disuse of the ovary?

A. Yes. Actually, they don't shrivel. They remain the same size but they cease functioning. [620]

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Together with a gradual cessation of the production of estrogen by the ovary?

A. That I don't know.

Q. Have you ever conducted any clinical research into this phenomenon?

A. No. I haven't.

Q. As to a male, if there were comparable symptoms or changes, wouldn't the testes take the place of the ovary? A. Roughly, yes.

Q. In other words, the testes would cease to produce their natural products? A. That is right.

Q. Which would be sperm and testosterone, is that not correct? A. Well, partly it is.

Q. Are not sperm produced by the testes?

A. Yes, but they are not necessarily diminished in later life.

Q. In other words, the testes do not change as do the ovaries?

A. They don't change in size and neither do the ovaries change in size.

Q. But the testes continue to produce sperm?

A. In some cases, in amazing quantities.

Q. But the ovary no longer produces the [621] ovum?

A. However, some investigators claim that it does.

Q. We are speaking of the general run of people. A. Yes; they are both similar.

Q. Doctor, what, if any, clinical or laboratory experience have you had in determining whether or

(Testimony of Dr. Paul Edward Travis, M.D.)
not the testes in a male past the age of say 50 continue to produce testosterone?

A. None whatsoever.

Q. Have you ever conducted any type of examination or analysis to determine what is the testosterone production of the glands of a male of that age?

A. No.

Q. You have had no experience along that line?

A. No; nor of a female on estrogen.

Q. Then, actually, how do you determine whether or not there is a deficiency of the male hormone in a male past that age?

A. Simply by subjective symptoms. In other words, you get the patient's story, and then, by trial and error, you use testosterone and, if they are relieved, you assume you have corrected a procedure or are using the correct procedure.

Q. You mentioned some symptoms. You mentioned loss of libido or diminution, loss of a sense of well-being, nervousness, irritability, that they don't sleep well and, "Doc, I just don't feel well." Those are the symptoms on which you [622] go, are they?

A. Some of the symptoms.

Q. Aren't some of those symptoms, likewise, the symptoms of fatigue or over-tiredness?

A. They can be symptoms of most anything.

Q. Tuberculosis?

A. Yes, and heart disease. They are general symptoms. They are not all present in all of these other diseases. You can pick out fatigue, which is certainly a symptom of many diseases. Nervousness

(Testimony of Dr. Paul Edward Travis, M.D.)

is a symptom of many other diseases. But they are not present in that same symptom complex. In other words, they are not all present at the same time.

Q. Are they all present at the same time in the instance of a male hormone deficiency?

A. Practically always; yes.

Q. But not invariably, apparently?

A. Oh, no. Nothing is invariable.

Q. Is that also true in symptoms such as flushes, sweats, chills, lack of sexual power, impaired memory, inability to concentrate on activities or a tendency to evade them, depression, general weakness and poor physical strength? Are they, likewise, a part of this symptom complex?

A. Yes; they can be.

Q. But they are not, necessarily? [623]

A. Not all the time; no.

Q. And, likewise, they are also symptoms found in the many other diseases to which you have just referred, is that not correct?

A. Some of them are; yes.

Q. As a matter of fact, isn't impotence the same thing you referred to as loss of libido?

A. It is usually a part of the picture.

Q. Is that what you had reference to when you mentioned a loss of libido? A. No.

Q. What did you refer to?

A. Loss of libido can be concerned with a sexual drive in other fields besides ability to have sexual intercourse.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. But would you consider impotence as being one of these——

A. A part of loss of libido; yes.

Q. You say that impotence can be overcome by male sex hormones? A. Yes; it can.

Q. Do you know whether there are other causes of impotence besides a deficiency of the male sex hormone?

A. One of the biggest of them is psychogenic and, if a person has lost his impotence by virtue of psychogenesis, a male sex hormone would not give it back to him. [624]

Q. What would give it back to him?

A. It might through suggestion, which makes it a therapeutic drug.

Q. Of course, a sugar pill would perform the same function, wouldn't it, if the man believed in its efficacy?

A. It is a marvelous drug sometimes.

Q. But the cause of the renewed potency would be psychological rather than the testosterone in that case? A. What do you mean by the cause?

Q. What would give him back his potency?

A. The drug through suggestion, because it is just as effective mentally as physically but——

Q. But a sugar pill would, likewise, wouldn't it?

A. Yes, sir.

* * *

The Witness: Of course, as a rule, men seeking a cure for impotency don't take sugar pills.

Q. (By Mr. Danielson): But in psychogenic cases one has worked the same as the other one?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes. We are interested in helping the patient and, if the patient gets relief, that is what we are after.

Q. But, so far as you are concerned, the sugar pill would work as well as the testosterone?

A. That is right. [625]

Q. It is the fact that the doctor is giving something that overcomes that?

A. Yes; plus massive doses of reassurance in many cases.

Q. Doctor, is it not true that the general indication for sex hormone therapy is to replace something that nature either has failed to provide or no longer provides in adequate quantity?

A. That is right. All hormone therapy is replacement therapy.

Q. Then, as a condition precedent to any bona fides, would be a shortage or a deficiency of the hormone?

A. Will you state that again, please?

Q. A condition which is prerequisite to any need for hormone therapy is a deficiency in the hormone, is that not correct?

A. Mentally or physically; yes.

Q. You have to be short of hormones before you need hormones in that case?

A. Or think you are short of them.

Q. We are talking about real factors rather than psychological at the moment.

A. You can't divorce the two. You have got to think of them together.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Doctor, you have stated, however, that replacement [626] therapy is the keystone of hormone therapy? A. Absolutely.

Q. And in making up for something which Nature is not now providing?

A. In sufficient quantity.

Q. In other words, in your testimony as to the Menformon Dosules or estrogenic ointment for cosmetic development of the bust, you stated that in a properly selected case you could expect favorable results. Just what do you mean by a properly selected case, Doctor?

A. A female past puberty. In other words, you can't take a young girl, because she hasn't even come into puberty. And we know that during puberty is when the female hormones start to increase. You have to take a female past puberty who has definitely shown her estrogen level is not going to increase to the point where she is going to develop the bust.

Q. That is a hypogonad, is it not?

A. Or just a lack of estrogens. You take a woman past say 18 or 20 and you know that they are not going to get any further development in bust through their own natural hormonal development. You are going to have to supply it.

Q. This is a person whom you have determined will not get further development through her own natural supply of hormones? [627]

A. Yes, sir.

Q. She is deficient in hormones, is she not?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes; she is.

Q. That is not just any normal woman walking down the street, is it? A. No.

Q. When you qualified your answer by saying "in a properly selected case," you were referring only to this woman who had a deficiency in hormones, is that not correct?

A. No. What I meant was a woman past puberty.

Q. And, likewise, deficient in the hormone, is that not correct, if she has a very small bust?

A. She is usually deficient in that.

Q. Will you answer my question? You were referring to a woman who is deficient in the hormones, is that not correct?

A. If she has a flat bust and she is deficient in hormones. That is what I mean.

Q. And if she is deficient in hormones?

A. Yes.

Q. Doctor, have you ever removed a prostate?

A. No.

Q. Have you ever treated anyone for carcinoma of the prostate?

A. Yes, I have. I have a patient under treatment now. [628]

Q. Are you using sex hormone therapy?

A. Yes; stilbestrol.

Q. That is the female hormone, is it not?

A. Yes; that is right.

Q. Would you feel safe in putting this man on testosterone at this time?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. I wouldn't hesitate; no.

Q. Have you done so?

A. No. But I wouldn't hesitate if it was necessary to relieve certain symptoms. [629]

Q. (By Mr. Danielson): Have you referred this patient to an urologist, by any chance, Doctor?

A. Yes, and the patient has come back.

Q. Now, you likewise stated, Doctor, that a busy general practitioner would not have time to conduct a very thorough physical examination, the type of physical examination which was described to you by Mr. Elson in the course of your examination?

A. That is right. It would take you roughly two hours.

Q. What is the usual examination for determining the presence of prostatic cancer?

A. You mean if the patient comes in to you?

Q. Yes, the ordinary, routine examination, what is that?

A. Well, if I suspect cancer of the prostate, I simply refer the patient to an urologist, but usually if you are just going through a routine examination, you do a rectal examination.

Q. A rectal examination, is it usual?

A. That is right.

Q. That is the one you refer to, is it not, as taking about 30 seconds? A. That is right.

Q. In other words, in about 30 seconds, the doctor can make the usual examination for cancer of the prostate? [630] A. Absolutely.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Don't you think that a very busy practitioner would not have time to do that, where a patient came in to a doctor and gave him a 30-second examination?

A. You usually do that, but you certainly do not take gastro-intestinal X-rays and make all the other special time-consuming examinations that the doctor mentioned.

Q. When you make your rectal examination and you find something which gives you suspicion of cancer, did you not just testify that you refer that man, then, to an urologist?

A. That is right. He has fewer patients and takes more time.

Q. And is more specialized?

A. That is right.

Q. And who conducts probably more thorough examinations on that particular point?

A. He follows the patient up, that is correct.

Q. In other words, as a general practitioner, you make this quick, the rectal examination. If you have, then, reason to suspect cancer, then you refer them to the specialist for the more detailed, more technical examination?

A. That is certainly right.

Q. Now, Doctor, you were asked as to testimony appearing on page 176 of our transcript, how is male hormone deficiency in any person determined—I am accenting the word [631] "determined" as opposed to trial and error or guesswork.

"A. Determined by first a careful history." Is

(Testimony of Dr. Paul Edward Travis, M.D.)

that an unusual situation? You always take the history of your patients, do you not, Doctor?

A. Oh, yes.

Q. "2. A careful physicial examination." When a patient comes to you and says, "Doc, I just don't feel well," you make a physical examination, do you not?

A. I start in there to go from head to toe, that is correct.

Q. And then, "3. There are some laboratory tests that will aid in diagnosis such as the estimation of the 17 ketosteroids in the urine." That is a specialized test, is it not? A. Yes, it is.

Q. Now, Doctor, you testified, however, on that point that a general practitioner would not have the time to perform these tests, because they are all specialized tests. You are really only referring to the one relative to the 17 ketosteroids, weren't you, Doctor?

A. That, plus a cystoscope examination would be considered specialized.

Q. By taking their history, plus the physical examination, you don't feel that they are specialized for the average practitioner, do you? [632]

A. That is right. You do those every day.

Q. Doctor, have you ever performed a biopsy on a patient, on the prostate?

A. No, sir, I haven't.

Q. But I believe you testified that you were not capable of performing one or at least not prepared to perform one?

A. That is right. I don't believe any general

(Testimony of Dr. Paul Edward Travis, M.D.)

practitioner is prepared to do a biopsy of the prostate in his office.

Q. And an urologist could perform one?

A. Yes, I imagine so, but I still think he would take the patient to the hospital.

Q. But he can perform it in the hospital or elsewhere? A. Oh, yes, he is capable of it.

Q. And did you not testify that when you suspect cancer of the prostate, you refer a man to an urologist? A. That is right.

Q. For further examination?

A. That is right.

Q. Now, as to cancer of the prostate, you testified that you can't diagnose it when it is incipient, yet, you also testified, Doctor, that you have diagnosed at least one cancer of the prostate, in treating a man. A. That is right. [633]

Q. About how large was it?

A. The cancer of the prostate?

Q. The cancer, yes.

A. It had consumed an entire lobe or half of the prostate.

Q. And you are treating it? A. Yes.

Q. Do you feel that a cancer can be diagnosed at an early stage so that it can be subjected to some beneficial treatment?

A. Even this one was at a far-advanced stage. Yet, he is getting benefit, very definitely, even though it was a far-advanced cancer when he came to me.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. If a cancer is diagnosed at an early enough stage, the earlier the diagnosis, the better the treatment, is that the theory on them?

A. That certainly is, especially in cancers.

Q. And the smaller you can catch them, the better off you are?

A. Well, size really does not have anything to do with it. It is its stage of growth, whether or not it is spread beyond its boundaries into other organs or things like that.

Q. So long as it is confined to its original situs and is fairly reasonably small, you can give some beneficial therapy? [624]

A. Well, size doesn't have anything to do with it, but as long as you say early cancer, when it is early, before it is spread to other organs, then is the time to get it and take it out.

Q. Would that be more or less the status of the one you diagnosed?

A. No. My man came to me with far-advanced cancer, with metastasis throughout his body.

Q. But they can be diagnosed before that spread, before that metastasis? A. Yes.

Q. And that would be considered in its early stage? A. Not too early.

Q. But fairly early? A. Yes.

Q. You have testified that there is quite a difference in opinion on the effect of testosterone on cancer of the prostate. I believe you testified that some doctors even say that testosterone will inhibit cancer of the prostate, is that right? A. That is right.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Will you state for me any such authority?

A. There was an article in The New England Journal of Medicine two years ago, and it was a symposium on male hormone and its effect on cancer of the prostate. I read it down at [635] Phoenix. The New England Journal of Medicine is, as you know, a journal conducted by the Massachusetts General Hospital, and they have many of the world's best authorities in various fields at that hospital. They had a symposium on the effect of male hormones on the prostate gland. And they had the consensus of opinion. They were very much divided.

Q. Would you say that this article contends that testosterone inhibits the growth of cancer of the prostate?

A. One man worked with, I believe it was monkeys, and had found that very, very large doses of testosterone had inhibited artificially produced cancer of the prostate.

Q. That is the gist of this article to which you are referring?

A. No. That was one of the points. It was a pro and con article, a symposium.

Q. That was one man's opinion based upon this experience with a monkey, in other words, is that correct? A. That is right.

Q. Rather than the gist of the article that you have referred to?

A. Well, the gist of the article was a symposium, with pro and con opinions.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. It was a group of various, varying opinions, in other words?

A. That is right. Everyone seemed to have a different [636] opinion.

Q. And the one to which you referred as saying that it inhibited the growth of the cancer of the prostate referred to this one man's experience with a monkey?

A. With a group of monkeys, yes, he ran a series.

Q. One man's experience with a group of monkeys.

To get back to the cosmetic effect on the busts of women, for one moment, is it not true, Doctor, that there are at least a few women, I would not say many women, who have flat busts and yet are not deficient in female hormone? A. Probably so.

Q. As a matter of fact, that is true, is it not, Doctor? A. It probably is, yes.

Q. Are you acquainted with Dr. Samuel Glass or are you acquainted with him by reputation?

A. I have read some of his articles, yes.

Q. Do you consider him to be an authority in this field?

A. I believe he is considered to be an authority, yes.

Q. I wish to understand one of your statements a little more fully. In your testimony, you stated in referring to a biopsy of the prostate, that if a such a thing were suggested to a patient, he probably would not come back again?

A. The general patient coming to a general prac-

(Testimony of Dr. Paul Edward Travis, M.D.)

titioner wanting relief from certain symptoms, if you start out mentioning [637] to him a surgical procedure, they begin to think that your real intentions are not all that they should be and they usually don't come back.

Q. But, as a matter of fact, there may be several things that a doctor may have to tell a patient from time to time which will either scare or disappoint at least a patient, isn't that true?

A. Oh, certainly, but you usually don't start out that way.

Q. In good professional practice, though, you would start and have to carry these things out, whether he liked them or not, wouldn't you?

A. We try not to start out that way, though.

Q. But, if a treatment were indicated, you would have to in the interest of your patient carry out whatever step was necessary?

A. You tell the patient that that step is necessary, but you don't carry it out, unless they consent.

Q. Sure, but nevertheless if a piece of surgery is necessary, regardless of whether the patient likes it or not, you are going to tell him it is necessary, aren't you?

A. That is right, but I don't consider routine biopsies of the prostate a necessary piece of surgery in any patient.

Q. Nevertheless, if you had a suspicion of cancer of the prostate, referred your patient to the urologist and [638] diagnosis became so obscure that it

(Testimony of Dr. Paul Edward Travis, M.D.)

was necessary to perform one, you would not hesitate to advise a biopsy?

A. No. If I suspected cancer of the prostate, I would certainly refer the patient to the urologist who would advise the biopsy.

Q. Regardless of whether the patient liked the idea, you would still tell him it was necessary?

A. That is right.

Q. In this case of the cancer of the prostate, you said in treating it, you used stilbestrol?

A. Dyethyl-stilbestrol.

Q. Why have you used stilbestrol on this patient?

A. Because it alleviates symptoms.

Q. As a matter of fact, isn't it because it tends to counteract the influence of testosterone?

A. I don't know, but it just relieves symptoms.

Q. But, as a matter of fact, isn't it true that the literature holds at least that the stilbestrol tends to counteract or offset the action of the testosterone?

* * *

A. I will say I don't know.

Q. You don't know? [639]

A. That is right.

Mr. Danielson: Very good. Thank you.

Q. Is it not true, in treatment of cancer of the prostate, that castration is frequently resorted to?

A. I have never in my experience had that happen—had to do that, no, sir.

Q. You have never done that? A. No, sir.

Q. Are you familiar with good medical practice along with treatment of cancer of the prostate?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes. I believe they are no longer doing castration in general out in private practice. That certainly is experimental. I believe Huggins in about 1941 started a series of cases in which he did orchiectomies, or castrations.

Q. Yes.

A. But I believe they have almost stopped doing that, now, because of the terrific psychogenic trauma that was produced, and now they are simply giving large doses, very large doses of dyethyl-stilbestrol.

Q. In other words, they use the stilbestrol to take the place of the castration, is that correct?

A. Apparently, yes.

Q. If you were to hear Dr. Elmer Belt testify that castration is practiced for that purpose, would that tend to change your opinion? [640]

A. Certainly, if in his practice he does that, that is fine. I would not certainly do it in mine.

Q. That would change your opinion as to whether or not it was still being practiced?

A. Still being praticed in office clinics.

Q. And if you heard Dr. Huggins testify to the same effect, that the same practice was still being practiced in 1949, would that change your opinion as to whether it was still in general practice?

A. No. Dr. Huggins happens to be connected with the University Hospital, in which he can, very frankly, get away with experiments.

Q. Now, I asked you a question.

A. No. It would not change my opinion.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Then, you would still say that castration is not in general practice today?

A. That is right.

Q. Even though Dr. Belt and Dr. Huggins gave testimony to the contrary?

A. That is right, because I know other urologists who would testify to the contrary.

Q. Have you ever conducted any analysis to determine definitely whether males over the age of say 50, this climacteric age to which you refer, do or do not produce testosterone? [641]

A. No, sir, I haven't.

Q. Now, as to sterility, you stated on direct examination that at 45 it is too late for a male to have children. You did not exactly mean that, did you, Doctor?

A. No. What I meant was that he usually doesn't prefer children at that age.

Q. By the way, you don't mean that a man is sterile at 45, whether he likes it or not, do you?

A. No, no. Many of them remain fertile at 86. The newspapers said so, anyway.

Q. And you also stated that the question of fertility has never come up in your practice, that is in men over the age of 45? A. That is right.

Q. Have you had very extensive practice in the field of sterility, Doctor?

A. I have conducted sperm counts and basal temperatures for couples desiring children, yes.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. Have you had a very extensive practice along that line?

A. About a dozen patients—couples, a dozen couples.

Q. As to those symptoms of the male menopause, again I don't wish to enumerate them, unless you wish. A. I remember them.

Q. I think we all have them in mind. What did people [642] use for the purpose of treating those symptoms prior to the advance of testosterone, Doctor? A. Probably sugar pills.

Q. And that has not been much over ten years ago, since testosterone became available?

A. Ten to 15 years.

Q. Recently in medical experience?

A. That is true.

Q. Sugar pills would have been the treatment prior to that time? A. Or Cascara, yes.

Q. Now, you mentioned in response to a question that you thought, as to the effect that testosterone would have sterility, that apparently in effect there were three schools of thought, some said it would produce sterility, some said it would not do anything in particular and others said it would increase fertility? A. That is right.

Q. What is your opinion on the basis of your training, experience and study?

A. Well, as I say, I have never examined a patient for sterility or fertility.

Q. You do not personally have an opinion as to that, as yet, is that correct?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Not for patients who wish relief for male climacteric [643] symptoms. I had one couple who desired a child and the husband had been a veteran in the South Pacific about five years and when he came back he was a little bit impotent and he also had very low sluggish sperm count, and upon administration of testosterone propiniate, which is another form of testosterone (you administer that by injection form twice weekly), the wife conceived and his sperm count subsequently became elevated and the sperm count became more motile, the sperms became more motile.

Q. Was that at Phoenix, Doctor?

A. No. This has been in my private practice.

Q. Now, do you have an opinion, Doctor, as to whether or not the use of testosterone will inhibit the generation of sperm or will increase the generation of sperm or will have no effect upon it?

A. I think it depends upon the age of the patient.

Q. You have no definite opinion on that, then, is that correct?

A. That is right, just from what I have observed in my own practice.

Q. Now, to get back to the uterine bleeding, the use of the alpha estradiol. Have you ever used these 5 milligram tablets of alpha estradiol on anyone, Doctor?

A. No. I prefer another preparation. I just happen to use another preparation similar to it. [644]

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. You have not used this particular preparation? A. No.

Q. But you have used a similar one, though, in your therapy, in your practice?

A. Oh, yes, many times.

Mr. Elson: Just a minute, counsel. I think you said 5 milligrams.

Mr. Danielson: .5 milligrams. I am sorry. Correct it to .5 milligrams.

Q. Is that the instance in which you mentioned producing uterine bleeding in three weeks time?

A. That is right.

Q. And I believe you stated by the patient's own volition the dosage was up to four tablets a day?

A. Yes. That was a Premarin, a preparation called Premarin.

Q. What is the concentration of that?

A. There are four concentrations put out by Ahert-MeKenna Company.

Q. What dosage was she taking?

A. She was taking 1.25 milligrams capsule nightly, which they put out, a 1.25 milligram capsule. She happened to be taking two of the .625, which is the same thing, and she doubled her dose just like many people think if two is going to do you good, four will do you better, and she commenced uterine [645] bleeding in three weeks.

Q. What it boiled down to in gross, she was taking 1.25 milligrams?

A. She was taking 2½ milligrams.

Q. 2½?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Yes, and she was taking four of the .625.

Q. And this daily produced the uterine bleeding?

A. In three weeks, yes.

Q. I understood you to say that this was sometimes a beneficial result, this uterine bleeding, indirectly?

A. Beneficial result because the patient returns to you. They are more worried.

Q. In other words, you have more business then, is that it?

A. No. You can catch something early that might be dangerous, such as cancer.

Q. And how do you detect that?

A. By this curettement.

Q. What does that consist of, Doctor, the curettement?

A. First of all, if the patient is on a female estrogen, you are going to take it off of it and see if her bleeding stops.

Q. Surely.

A. If it doesn't stop, then you have to go ahead and determine why she continues to bleed, and one of the simplest [646] methods is simply to scrape out a lining of the womb and examine the cells in the lining of the womb microscopically. That will tell you whether you are dealing with a hyperplasia, with excessive amount of lining of the womb, or whether you are dealing with a malignant process such as cancer.

Q. And that is removed?

A. You do that in excessive bleeding.

(Testimony of Dr. Paul Edward Travis, M.D.)

Q. And you do that, then, in order to determine what is the persistent bleeding of the patient?

A. If just upon removal of the female estrogen, she doesn't cease to bleed.

Q. In many of those cases, apparently you do not actually find cancer, then, is that correct?

A. That is right.

Q. And in those cases the surgery has been necessitated for no good reason, has it, Doctor?

A. It certainly relieved yourself and the patient, if she doesn't have cancer.

Q. What is that?

A. You have relieved yourself and the patient that she does not have cancer. Of course that is what brings them in to you, she is worried about cancer. They have already read articles in magazines that uterine bleeding is one of the cardinal signs of cancer of the womb. And if upon cessation of the female hormones, they don't cease bleeding, the woman [647] soon comes in to see you and inquires about whether or not she has cancer. And to put her completely at rest, you must do a curettement.

Q. (By Mr. Danielson): But, in the cases in which there was no cancer found upon this curettement, the surgery——

The Witness: Then usually they stop——

Mr. Danielson: May I ask the question? In other words, in these cases in which you find no cancer, the surgery has been more or less unnecessary, hasn't it?

A. No. You find something else that causes

(Testimony of Dr. Paul Edward Travis, M.D.)

bleeding, such as a polyp or fibroid or a paraplastic due to some other causes.

Q. Are you familiar at all with the work of Dr. Robert A. Kimbrough, an M.D.?

A. No, I am not.

Q. And Dr. S. Leon Israel, M.D. of Philadelphia? A. No, I am not.

Q. And have you, by any chance, read an article entitled The Use and Abuse of Estrogen, appearing in the Journal of the American Medical Association, December 25, 1948?

A. No, sir, I haven't read that article.

Q. I would like to ask you a question there. On page 7 of that article, there is this statement:

"The unfortunate faculty of estrogen of inducing uterine bleeding in the postmenopausal woman is indirectly responsible [648] for many instances of neglected carcinoma of the uterus." Do you agree with that statement, Doctor?

A. No, I don't, because a woman bleeding from the womb will come in to you and you will be able to make a diagnosis. If you are a conscientious practitioner, you will withdraw the drug from use and if she does not cease to bleed, then you will investigate the bleeding.

Q. Supposing she buys this drug on being under your supervision, then, Doctor?

A. Then she starts to bleed, then she comes in to us.

Q. It will still cause the bleeding?

(Testimony of Dr. Paul Edward Travis, M.D.)

A. Oh, absolutely. Then they come in to you and you start from there.

Q. And it is true, is it not, sometimes the uterine bleeding is brought about by just the use of the hormone?

A. Oh, yes, in many cases uterine bleeding may be produced by the estrogen.

Q. Then, if any person developed uterine bleeding and attributed it to the use of the hormone, they would probably come in to have an examination made, then, would they not?

A. Well, what they probably would to would be to stop the hormone and if the bleeding continued, then they would become worried and seek medical advice.

Q. On the basis strictly of your familiarity with the use of these products, Doctor, would you advise one of such [649] patients, either a woman of this period to which we have just referred or a man in this male climacteric to which we have referred, to take such amounts of these hormones as he might wish, without the continued advice of the doctor?

A. They are certainly harmless and in prescribed doses they are perfectly all right, yes.

Q. And in non-prescribed dosages, to diagnose himself and buy his own, or her own amount of hormone as he or she wishes, would you advise that to any of these groups?

Mr. Elson: He is talking about something that is not in issue in this case, about no prescribed dosages.

(Testimony of Dr. Paul Edward Travis, M.D.)

The labeling of goods says dosage so much a day. Don't you think we had better confine it to that?

Mr. Danielson: The 25 milligrams per day for males, 25 milligram tablets, two or three for males?

A. That is perfectly all right.

Q. Just go ahead and diagnose themselves and use them at will, is that correct?

A. Well, people do.

Q. I am asking you what you recommend, not what people do. Do you recommend that?

A. Do you mean if the patient comes in to me and asks me?

Q. No. Just any person.

A. I see no harm in it. [650]

Mr. Danielson: Very well. No further questions.

Re-Direct Examination

By Mr. Elson:

Q. Mr. Danielson asked you if in substance, you were informed that Dr. Huggins and Dr. Belt advised that castration was a present-day practice in connection with cancer of the prostate, would your opinion be changed in that way? Now, I will ask you if you were told that Dr. Heckel stated in substance, "However, men are castrated every day for the purpose of inhibiting the growth of cancer of the prostate, although not as many men are castrated as they were five years ago," would you be inclined to agree with that statement?

A. That is what I stated, yes.

Mr. Elson: That is all.

* * *

DR. WILLIAM A. SWIM

called as a witness by and on behalf of the defendants, having been first duly sworn, was examined and testified as follows:

The Clerk: Your full name?

A. William A. Swim. [651]

Direct Examination

By Mr. Elson:

Q. Dr. Swim, you are a doctor of medicine?

A. I am.

Q. Will you please state the schools that you attended?

A. I attended the University of Chicago, undergraduate, Rush Medical College.

Q. And did you graduate from Rush Medical College? A. Yes, I did.

Q. And was it from that institution that you got your M.D. degree? A. It was. [652]

Q. In what year? A. 1915.

Q. And then, thereafter, were you associated with any institutions, hospitals or the like?

A. Yes.

Q. Will you state what they were?

A. Well, I had an interneship at Milwaukee Sanitarium for mental and nervous diseases, a period of one year at Los Angeles General Hospital, and the New Haven Hospital connected with Yale for a period of about seven months.

(Testimony of Dr. William A. Swim.)

Q. And you were in World War I for a time, were you? A. Yes, I was.

Q. And when did you come to Los Angeles?

A. In 1915.

Q. And when did you commence the practice of medicine in Los Angeles? A. In 1918.

Q. And was it in any particular branch of medicine, or what?

A. Yes. I have practiced internal medicine since then.

Q. Will you describe what internal medicine is?

A. Well, internal medicine consists of diagnosis and the treatment of non-surgical diseases, non-obstetrical.

Q. Are you connected with any state boards at the [653] present time?

A. Not at the present time.

Q. Have you ever been connected with any?

A. Yes.

Q. Will you state what it was?

A. I was a member of the Board of Medical Examiners for four years.

Q. Of this state? A. Yes.

Q. Now, Doctor, if an individual comes to you, say a male in middle life, and complains of nervousness, flushes, sweats, chills, general weakness, lack of physical strength, impaired memory, inability to concentrate on activities and a tendency to evade them, not necessarily all of those symptoms, what is your practice in dealing with that patient and his symptoms?

(Testimony of Dr. William A. Swim.)

A. Well, I take a general history of the present illness and the patient's past illnesses. I make a physical examination, including the head and neck and chest and abdomen, the prostate and rectum, the reflexes, the general appearance of the skin, and if I find no evidence of any constitutional disease of a specific nature, I prescribe testosterone or administer it.

Q. You mean you inject it? A. Yes. [654]

Q. Is it your usual practice to inject it rather than to prescribe it in tablet form?

A. I usually inject it.

Q. And have you done so on one or on many occasions? A. On many occasions.

Q. Over the period of practice that you have been here, since there has been testosterone?

A. Since there has been testosterone, with ever increasing number of cases.

Q. The testosterone has been available, let us say, in commercial quantities, during the past ten years or so, hasn't it? A. I believe so, yes.

Q. Now, on many of those occasions, have you found, after having administered testosterone, that the person's symptoms appeared to be relieved?

A. On many occasions, yes.

Q. On any occasion on which you have ever administered testosterone to a person, have you ever encountered what you considered were adverse results? A. Never.

Q. You understand the meaning of male climacteric? A. I think I do.

Q. And what do you associate that term with?

A. With a diminuition of the secretion of the interstitial [655] cells of the testicle.

Q. And does that occur with young men, men in middle age or in old men?

A. Usually in a man around 50.

Q. And those men complain of what symptoms, usually?

A. They complain of fatigue, lack of concentration, loss of memory, loss of appetite, sleeplessness, sometimes a sense of heat in the body, and profuse perspiration.

Q. The other day one of the witnesses for the government stated as follows (pages 39 to 41) that: Assuming a man to be 50 years of age, who complains of flushes, sweats, extreme nervousness, inability to concentrate, nocturia, and he goes to his doctor who is a general practitioner, no evidence of cancer of the prostate is diagnosed, he does not believe that the doctor would prescribe testosterone for a period of time, and wait and see whether the symptoms were relieved, and before he could answer that the practitioner would prescribe it, he would have to know more of what the examination consisted and what the urologist may have done by way of examination, if the urologist report was that he had palpated the prostate and performed a biopsy and found no evidence of cancer of the prostate, and no enlargement of the prostate and laboratory tests showed that there was a marked decrease in the secretion of testosterone, even then, in his opinion, testosterone would not be prescribed

(Testimony of Dr. William A. Swim.)

by [656] the man's doctor unless there was further evidence of the male climacteric.

Now then, assuming that that same individual came to you and complained to you, being a man of 50 years of age, would you follow through the elaborate procedure described by that doctor?

A. No, sir.

Q. What would you do?

A. Just what I have already indicated, I would make a physical examination and a rectal examination and if I found no tumor mass in the prostate, I would prescribe testosterone.

Q. By the way, do you believe that it is possible to diagnose or detect an incipient cancer of the prostate? A. It is not possible.

Q. What size does a cancer of the prostate have to be, before you are able to find it by palpation?

A. Well, I would say the size of a walnut.

Q. A small or large walnut?

A. A medium sized walnut.

Q. In the practice of medicine—oh, by the way, with this individual that we have just talked about on that elaborate test that this other doctor mentioned, what in your opinion would be the attitude of the average patient if such procedure were suggested for the relief of those symptoms? [657]

A. I think he would not follow through. He would probably refuse to go through the procedure, unless he felt definitely that a diagnosis of some malignancy had been made.

Q. And thereupon either go to some other doctor

(Testimony of Dr. William A. Swim.)

who would do it without that procedure, or go unrelieved? A. Yes, I think so.

Q. Now, in the practice of medicine, do you consider that medical work is, in the great majority of instances, specific or is it hypothetical?

A. In many instances, it is hypothetical, in the majority of instances.

Q. Are there many specifics, in medicine?

A. Not many.

Q. Specific treatment for a specific condition which you know is going to produce that result, there is no question of it? A. Not many.

Q. From your experience, do you consider that enlargement of the prostate as a rule indicates a cancerous condition? A. No.

Q. What do you consider that it indicates, as a rule?

A. Benign hyptertrophy of the prostate.

Q. And what is that? [658]

A. Which is simply an overgrowth of the prostatic tissue. Some call it a tumor.

Q. I don't think I asked you this, but if I did I am going to ask it again anyway: In your practice, approximately how often, how many times per week do you prescribe testosterone, just approximately? A. Oh, once a week probably.

Q. Have you ever injected testosterone propionate into doctors of medicine? A. Yes.

Q. On one or more than one occasion?

A. On more than one occasion.

(Testimony of Dr. William A. Swim.)

Q. And prior to that injection, did you conduct a rectal examination? A. No.

Q. Did the doctors ask for it? A. No.

Q. Now, there was a doctor the other day who testified for the prosecution, Dr. Heckel, page 173, that in his opinion men in middle life do not generally have a deficiency of male sex hormone. Do you share the opinion of that doctor?

A. I do not.

Q. Will you state why?

A. Well, I think men of middle age do have a deficiency, [659] that is, their concentration of their hormone is below its maximum.

Q. Take this individual in whom you inject testosterone propionate and he comes back in three to four weeks or something like that and the symptoms have disappeared or have been relieved, what conclusion would you come to?

A. That I had supplied him with a hormone that he had been deficient in.

Q. And if that man came back and the symptoms were not relieved, what would you do?

A. I might change the dose. I would change the dose.

Q. And if that kept on and no result was accomplished, would you try something else?

A. Yes, I would.

Q. As a matter of fact, in the practice of medicine, it is to a large extent trial and error, is it not?

A. It is, yes.

Q. Now, Doctor, Dr. Heckel stated the other

(Testimony of Dr. William A. Swim.)

day (page 176) that a male hormone deficiency is determined, first, by a careful history; second, a careful physical examination and, third, laboratory tests to aid in diagnosis, such as the estimation of 17 ketosteroids in the urine, also such deficiency is determined by the estimation of the excretion of gonadotropins also in the urine. Is it your practice to conduct such a test to determine whether a man has a hormone [660] deficiency, prior to administering testosterone to him?

A. No. It is not.

Q. By the way, in your practice, are you aware of any other doctors in this locality that conform to such tests? A. I am not aware of any.

Q. Now, also, Dr. Heckel stated (I don't find the page, but I remember it distinctly) that in the case of an early or incipient cancer of the prostate, it might require a biopsy of the prostate to determine its existence. Have you had any experiences where a biopsy of the prostate has been performed to determine whether or not a cancer of the prostate existed? A. No. I have not.

Q. And, by the way, if a biopsy of the prostate was made, would that necessarily and conclusively determine that there was a cancer there?

A. It would not necessarily.

Q. Wouldn't it be possible that the tissue that was taken out from the prostate would not be part of the tissue that was infected, if it were infected?

A. That is true.

(Testimony of Dr. William A. Swim.)

Q. In your practice, approximately how often do you encounter a cancer of the prostate?

A. Very seldom.

Q. And by that what do you mean? [661]

A. I think I have seen three in my practice.

Q. Now, the other day this same doctor, Dr. Heckel, stated, on page 186, as to a patient coming to a general practitioner, complaining of the several symptoms, nervousness, fatigue, loss of memory, inability to concentrate and so on, such as we have discussed, in Dr. Heckel's opinion the practitioner would make a careful examination of the patient to see if he could find out what is producing those symptoms, he would conduct a complete physical examination from head to foot, he would examine the urine to see whether there was any sugar in it, which might give him a clue that this patient might have diabetes, which would produce such symptoms. If there were no sugar, then he would look at the urine to see whether there was albumin in the urine or casts in the urine, which would indicate that the patient, in all probability, would be suffering from Bright's Disease or some kidney disturbance. If nothing turned up, then he would take the patient's blood pressure and if that was normal, there might be some indication that the patient had a gastro-intestinal disturbance and an X-ray picture of the stomach or an X-ray picture of the colon would be taken or a basal metabolic test made to discover whether or not he had some disturbance of his thyroid. If such a doctor found

(Testimony of Dr. William A. Swim.)

nothing suspicious as a result of such a complete examination, he might, but he shouldn't suggest testosterone [662] to the man for a period of four to six weeks, to see if those symptoms were relieved.

Do you agree or do you disagree with the opinion of Dr. Heckel as to what the practitioner would do?

A. I disagree.

Q. Have you ever done such a thing prior to administering testosterone for those symptoms?

A. No.

Q. Do you know of any doctor in your experience who has done so, other than in the experimental field? A. No.

Q. Now, have you had occasion to review the literature on the subject of testosterone in its relation to cancer of the prostate?

A. I have read some articles, yes.

Q. Now then, as a result of your reading, as a result of your experience in the practice of medicine and as a result of your contacts with other doctors and meetings with them, in your opinion, will testosterone propionate at 25 to 50 milligrams a day accelerate the growth of an incipient carcinoma of the prostate? A. No.

Q. In your opinion, is such a quantity of testosterone taken orally, daily, dangerous?

A. No. [663]

Q. Now, testosterone is a natural product, isn't it, in the male? A. Yes.

Q. Is it possible for you, on the basis of your experience, to tell how much testosterone over and

(Testimony of Dr. William A. Swim.)

above that which an individual produces, would be necessary to accelerate the growth of any kind of a cancer? A. No.

Q. Why is that? Why is that?

A. Well, in the first place, cancer has no particular line of progress. It is the one lawless thing that we have in human pathology. A cancer may lay dormant for many, many years. It may flare up, without any apparent provocation and grow rapidly and destroy life in a very short time.

I had one case that was turned over to me to give morphine, for palliative treatment, during her last months after she had surgery and had X-ray treatment and had been given up as a possibility of a saving. I gave her a quarter of morphine, about one a day. Three years after that time, a cancer expert could find no cancer in her and she died six years later.

Another case of cancer of the breast, who had some other complications that contra-indicated surgery at the time, developed metastasis so rapidly without any benefit, without any treatment with testosterone or any other hormone, without [664] any specific hormonal treatment, that she was inoperable by the time these complications had been corrected.

Q. That reminds me, two or three of the other doctors for the government here have spoken of cancer of the prostate and cancer of the breast following a usual pattern of growth. In your ex-

(Testimony of Dr. William A. Swim.)

perience, have you ever found cancers of any kind to follow a usual pattern? A. No.

Q. Will you explain that?

A. Well, they are just simply lawless. One never can tell. We do not understand the pathology of cancer and we do not have any orderly procedure. We just simply cannot put the course of cancer down like we can the course of infections, infectious diseases, because they vary too much from any average, so as to make what we might call the average worthless to follow.

Q. If cancers did follow a usual pattern of growth, in your opinion would that assist the doctors in being able at least to control it to some extent? A. It would, I think.

Q. Now, coming to the subject of sterility, I think I told you that the complaint here charges that 25 to 50 milligrams methyl testosterone daily is dangerous because it may cause sterility. Now, in your experience, have you ever found testosterone to cause sterility, in an individual? [665]

A. No.

Q. What is the average age of an individual male coming to you for testosterone?

A. About 50.

Q. Have you found in those persons the subject of fertility or sterility to be an important factor as compared to relief from the symptoms of which they were complaining?

A. Not an important factor.

(Testimony of Dr. William A. Swim.)

Q. By the way, are vasectomies frequently done?

A. I don't know how frequently. I know of several that have been done.

Q. And a vasectomy is what?

A. Is a severing of the spermatic tube that leads from the testicle to the vas deferens.

Q. And a man who has had a vasectomy performed is unable to produce children?

A. That is right.

Q. And have you found that to be something that has been voluntarily applied for by the individual? A. Yes.

Q. And for what purpose?

A. Well, as a contraceptive measure, to prevent having children. Once in a while, for less noble reasons.

Q. Now, one of the government witnesses, a doctor, Dr. Nelson, testified as follows, on page 99. He was testifying [666] or questions were being asked him about the effect of methyl testosterone upon sperm cell production and the production of testosterone by the interstitial cells and this question was asked him:

"Q. How could it, then, be determined whether or not there had been any damage to the testosterone-producing portions of the testes?

"A. The only way one can ascertain that is by examination of the testes and looking at the interstitial cells, noticing the atrophic changes that have been promoted by the inhibiting influences of the administered testosterone.

(Testimony of Dr. William A. Swim.)

"Q. Is that the microscopic examination of a slide a portion of the testes——

"A. Yes, sir——

"Q. Under a slide?

"A. Yes, sir.

"Q. (By the Court): Just how do you get at that? How do you examine the testes under a slide?

"A. A small piece of the testes is removed.

"Q. (By the Court): By surgical operation?

"A. By surgical operation, usually under a very simple local anesthetic. The tissue is properly fixed and sectioned and stained, the usual pathological procedure.

"Q. (By the Court): How would that be called for except by just some experiment? That does not seem like a practical [667] thing. Who would have that done?

"A. It is being done very, very widely, now.

"Q. It is?

"A. In cases of infertility or sterility or suspected disease or abnormal function of the testes. It is a widely recognized procedure at the present time."

Now, Doctor, in the practice of medicine, other than in the experimental field, I will ask you, is such a procedure widely done?

A. No, I believe not.

Q. Do you know of any instances where it has been done? A. No, I do not.

Q. Now, Doctor, have you had occasion to read

(Testimony of Dr. William A. Swim.)

some of the literature on the subject of testosterone and its relationship to sterility?

A. Yes. I have read some.

Q. Now, as a result of that reading, what opinion do you have as to whether or not testosterone will affect a man's sterility?

A. In my opinion, it will not affect sterility.

Q. Now, in the literature that you have read, has the opinion been uniform or does it appear to be divided? A. Divided.

Q. Two of the doctors that testified for the government, [668] Dr. Macdonald and Dr. Glass, stated unqualifiedly that estrogen is absolutely necessary to the growth of breast cancer. Now, I am going to ask you if, in your opinion—I am going to ask you if it is a fact that estrogen is absolutely necessary to the growth of breast cancer, or whether it is a matter of opinion, in your opinion.

A. In my opinion, it is quite a matter of opinion. In my opinion, it is not necessary.

Q. Will you state why?

A. Well, it is my own practice. I have seen cancers develop in the breast following what I thought was an absence of estrogen in the person.

Q. (By Mr. Elson): Now, Doctors Macdonald and Glass, and I am sure I am correct in interpreting the testimony, stated that the reason for their opinions in that connection was that the cancer following the administration of estrogens did not follow the usual pattern. Do you consider that to be a valid reason for their opinions that estrogen

(Testimony of Dr. William A. Swim.)

is absolutely necessary to the growth of breast cancer? A. No. There is no usual pattern.

Mr. Danielson: What is the page on that, Mr. Elson?

Mr. Elson: I don't know but, if you want to wait a minute, I can find it.

Mr. Danielson: If you can find that conveniently, I wish you would.

Mr. Elson: I can't find it conveniently but I can find it. It is on page 131. He stated he had, through diagnosis, treated such cases in which there was an affectation of this cancer or carcinoma; that these were young women with existing proved cancer of the breast, in which the duration of the cancer and its approximate rate of growth could be determined within reasonable limits; that, after the administration of the female sex hormone, and within a short time thereafter, there occurred in each of these instances to which he referred, a very rapid and alarming increase in the growth pattern of this breast cancer.

Mr. Danielson: That is referring to the administered [670] hormone as opposed to the other estrogen, isn't it?

Mr. Elson: I am talking about the natural. But I don't want to misinterpret the record.

Q. I will ask the witness do you believe, without the administration of estrogen—strike that. Do you believe that the natural estrogen in a woman's body is absolutely necessary to the growth of a breast cancer? A. No, sir.

(Testimony of Dr. William A. Swim.)

Q. Would it be for the same reasons you have stated? A. Yes.

Q. Doctors Macdonald and Glass stated that, in their opinion, estrogen administered caused breast cancer to accelerate in growth because the cancer did not follow a usual pattern. Now, do you believe that is a valid reason for their statement that estrogen is absolutely necessary for the growth of a breast cancer? A. I do not.

Q. Doctor, one of the products involved here is a half milligram of alpha estradiol, three tablets a day, which would be 1½ milligrams per day. In your opinion, would that be a dangerous dosage insofar as causing the acceleration of an incipient cancer of the breast, cervix or uterus?

A. It would not.

Q. By the way, in your opinion, is it possible to diagnose or discover an incipient cancer of the breast, [671] cervix or uterus? A. No.

Q. Another product involved here is alpha estradiol in the quantity of .1 milligrams, to be taken three tablets per day for 10 days and thereafter one per day. In your opinion, would that amount be dangerous to the individual taking it?

A. No.

Q. Assuming that after taking that product uterine bleeding resulted, would you consider that uterine bleeding, if it had resulted from that, was dangerous to the woman? A. No.

Q. Why not?

A. Well, it is like normal menstrual bleeding,

(Testimony of Dr. William A. Swim.)

occasioned by the same process. It will stop when the drug is stopped. So it couldn't possibly affect her.

Q. And, if a woman started to bleed and came to you, what would you do?

A. If she had not been taking hormones—if she had been, I mean—I would stop the hormones.

Q. Then, what would you do following that?

A. If she stopped bleeding, I wouldn't do anything. If she needed hormones, I would give a smaller dose.

Q. Do you believe, then, that uterine bleeding, that caused by alpha estradiol, is of any danger to the patient herself? [672] A. No danger.

Q. Are you familiar with these dosules that are used for breast development?

A. I am not familiar with them.

Q. Have you used them at all?

A. No; I have not.

Q. Dr. Heckel stated, on page 173, that, if testosterone were administered to a normal person, it would destroy the semeniferous tubules. Do you agree with Dr. Heckel in that statement?

A. I do not.

Q. Why don't you?

A. I have administered testosterone to people who have not borne children for years and had children born thereafter. So there must have been semeniferous tubules left.

Q. In other words, semeniferous tubules are

(Testimony of Dr. William A. Swim.)

absolutely necessary in order that a woman may produce? A. That is right.

Q. Doctor, let me ask you, in your opinion, would .1 milligrams of alpha estradiol, taken three times a day for a period of 10 days and thereafter one per day, have any effect in relieving a woman of the symptoms of the menopause?

A. Yes; it would.

Mr. Elson: You may cross-examine. [673]

Cross-Examination

By Mr. Danielson:

Q. Doctor, you say you are practicing internal medicine? A. Yes.

Q. Which is non-surgical, is that correct?

A. That is right.

Q. Do you perform any surgery, Doctor?

A. No.

Q. Then I take it you haven't removed any prostates?

A. Not since I was an intern.

Q. That would be not since 1918, is that right?

A. That is right.

The Court: Where is your place of practice?

The Witness: The Pacific Mutual Building, 523 West Sixth Street.

The Court: It is right downtown?

The Witness: Yes.

The Court: And what is the general nature of your clientele, of your patients?

(Testimony of Dr. William A. Swim.)

The Witness: I have a private practice of about 70 per cent; industrial accident work with various and sundry insurance companies of about 15 per cent; examination for unemployment insurance for the State of about 5 per cent, and examination and reports on injury cases of about 5 per cent. [674]

Q. Doctor, do I understand you to say that in your more or less 31 years of private practice here in Los Angeles you have discovered only three cases of cancer of the prostate? A. That is right.

Q. How long ago were they?

A. Well, one of them was shortly after I went into practice; one of them was about 10 years ago and one three years ago.

Q. You do not practice as an urologist, do you, Doctor? A. I do not.

Q. Nor specialize as an endocrinologist or gynecologist?

A. No. There is a difference, however, if I may explain that difference.

Q. You may, Doctor.

A. Endocrinology is a definite part of internal medicine, whereas urology is not any part of it.

Q. You do not specialize in the endocrinology phase of internal medicine?

A. No. I do general internal medicine only.

Q. And I believe you do no gynecology, is that correct?

A. I do medical gynecology but not surgical gynecology.

Q. Since you do no work as an urologist, I gather

(Testimony of Dr. William A. Swim.)

it is correct that no doctors would refer patients with [675] prostatitis or any other prostatic disturbance to you for treatment, would they?

A. I have had cases referred to me for treatment for prostatitis. And I must correct that one classification. I suppose there is such a thing as medical urology. We don't think of it quite in that term but there is such a thing. And prostatitis is an infection that can come in either field, either in the field of surgery or in the field of medicine, but it doesn't really involve in most cases the use of surgical instruments.

Q. No one refers surgical prostate cases to you, is that correct? A. That is correct.

Q. And these three cancer cases to which you have referred would be the sum total of your professional experience in cancer of the prostate, is that correct? A. Yes; that is correct.

Q. Then, Doctor, actually you have conducted no clinical or laboratory research into the effect of hormones on cancer of the prostate, have you?

A. That is right; I have not.

Q. And one of these cases took place shortly after you started practicing? A. Yes.

Q. In other words, there would be not more than two in [676] the last 10 years?

A. That is right.

Q. Two during the period of testosterone, in other words? A. That is right.

Q. And your opinion as to whether or not testosterone would accelerate the growth of a carcin-

(Testimony of Dr. William A. Swim.)

oma of the prostate would have to be confined to your observations of these two cases at the most, then, is that not correct?

A. Yes; it would be, personally.

Q. You did mention that in the case of a physical examination of a person coming in—do you know what I mean when I refer to the middle-aged symptoms? A. Yes.

Q. A patient coming in with these middle-aged symptoms, to which you are referring. You mentioned that in your practice you take a history, is that not correct? A. That is right.

Q. Did you perform a physical examination, enumerating the various parts of the body generally, including the reflexes and the appearance of the skin and examination of the prostate?

A. And the rectum; yes.

Q. You, likewise, testified, Doctor, that, if there was no indication of a malignancy, you would not go into the [677] more detailed examination such as biopsy and so forth? A. That is right.

Q. Doctor, in case there was some suspicion of malignancy, would you treat that yourself or would you refer the person to an urologist?

A. I would refer the patient to an urologist.

Q. In which event the urologist would conduct such additional examination as would be necessary to make a definite diagnosis, is that not correct?

A. That is right.

Q. And, if that required a biopsy, the biopsy would be performed, is that not correct?

(Testimony of Dr. William A. Swim.)

A. It might be. I don't know. I am not an urologist.

Q. That would be within the field of an urologist rather than the internal medical doctor?

A. Yes; it would be that field. But I am not sure whether it is still experimental or practical.

Q. When you testified as to this examination which you regularly conduct in your practice, you mentioned that, if there is no evidence of a constitutional disease, you would then administer or inject testosterone. Now, what did you refer to by "constitutional disease," to make that a little more clear?

A. Heart disease, chest diseases, like tuberculosis, and cirrhosis of the liver, diseases of the gastro-intestinal [678] tract, such as ulcer or cancer, and pancreatitis. I could continue the rest of the day with it.

Q. I suppose that is a good cross-section?

A. Yes.

Q. Doctor, in those cases would the use of testosterone be contra-indicated?

A. Not contra-indicated but would not be necessarily indicated.

Q. I see. Those conditions can, likewise, produce some of these symptoms we are referring to as the middle-aged symptoms, is that right?

A. Yes; they might contribute definitely to the production of those symptoms because they would help to lower the vitality of the interstitial cells of the testicle.

Q. And, likewise, these symptoms are not neces-

(Testimony of Dr. William A. Swim.)

sarily the exclusive indicia of the male climacteric, are they?

A. I believe that generally on the whole they are. I don't believe that they are a hundred per cent any of the other illnesses that I have mentioned.

Q. Yet you have testified that these other illnesses can produce these symptoms, isn't that correct?

A. They may produce some of the symptoms but not that complete symptom complex you have outlined there as the middle-aged disease.

Q. In your reference to this male climacteric or male [679] menopause, I believe you stated that you felt that there is a deficiency in male hormones in most men past the age of 50, or words to that effect? A. Yes; I believe there is.

Q. And, likewise, when you have one of these cases which you say appears to indicate the use of testosterone, you give the patient a certain dosage and let him take it for a reasonable length of time and then, on the basis of trial and error, if that does not work, you quit it and give him something else, is that correct? A. That is right.

Q. Now, let's take that one step farther. What would be one of these other things you would give him?

A. Well, I might give him bromides.

Q. And then suppose the bromides didn't work. Would you quit that and give him something else?

A. I might give him psychotherapy.

(Testimony of Dr. William A. Swim.)

Q. Suppose even that psychotherapy was lacking. What then?

A. We have patients that, no matter how many things we try, we have to keep on trying as long as the patient stays with us. No matter how long we try or what we try, we don't seem to be able to overcome certain symptoms that they complain of, which we designate as nervous symptoms.

Q. You mentioned about psychotherapy. Do you find, [680] Doctor, that sometimes the symptoms, no matter what kind of a pill you give a person, it might have a beneficial effect, just on a psychological basis.

A. Well, there may be a few patients who will react that way. I have never found that. I mean that would respond to pill therapy alone, because we have methods of detecting whether they respond to the real thing or spurious therapy.

Q. Doctor, you mentioned about the hormones being in short supply in many men past the age of 50. Just how do you determine that there is a deficiency in the male hormones.

A. By the clinical symptoms.

Q. Have you ever conducted any tests to determine whether a man's body is producing his requirements along that line? A. No; I haven't.

Q. Have you ever conducted any research on this either in a laboratory or clinically?

A. No; I haven't.

Q. Would that statement apply to all of this

(Testimony of Dr. William A. Swim.)

hormone field, that is, not conducting research, that is, the female as well as the male?

A. I will say yes, it applies. Research, of course, is a broad subject. I will have to correct myself in saying that, when we try one thing and then another, that is research. [681]

Q. I suppose that everything one does is in a way research.

A. Yes. I wanted to make that clear; that is all.

Q. I am referring only to what you might call planned or formal research.

A. I have not done that. I am not in research practice.

Q. Doctor, you are aware, of course, are you not, that it is possible by laboratory means to determine whether a person produces testosterone?

A. It is possible to determine by laboratory means whether a person produces testosterone at the particular time the test is taken, yes, at the particular moment the test is taken. That is quite possible.

Q. And is it not also true, Doctor, that if it were essential to determine whether or not a person were deficient in hormones or was without hormones, as the case may be, if it were necessary to make a definite determination, you would have to perform some such laboratory experiment or analysis?

A. If it were necessary. But I do not believe that it is necessary and I don't believe that it gives us any information after it is performed.

Q. But, to get back to the question, Doctor, if it were [682] necessary to determine whether or not

(Testimony of Dr. William A. Swim.)

a person's gonads were producing the testosterone, then it would also be necessary to conduct such laboratory analysis, would it not?

* * *

Q. (By Mr. Danielson): I will repeat it. If it were necessary to determine, Doctor, definitely whether or not a person's body was producing testosterone, that determination would have to be made through laboratory analysis? A. Yes.

Q. It is, likewise, true, is it not, Doctor,—strike that. Do you know of any laboratory analysis that will determine that fact other than the testicular biopsy? A. No; I don't.

Q. Doctor, as to carcinoma of the breast in a female, have you ever seen carcinoma in the breast of a hypogonad woman? A. Yes.

Q. In one who does not have her natural supply or who has not had her natural supply of estrogen?

A. Oh, no; I never have, as I remember.

Q. You may have seen it in a castrate woman?

A. I don't remember having seen one in one who has [683] never had estrogen.

* * *

Q. Have you ever seen a cancer in the breast of a woman who has not had some supply, natural or artificial, of estrogen over a fairly long period of time in her life? A. Yes; I have.

Q. How long a period of time?

A. Ten years.

Q. Ten years would be the shortest period of time which you can presently recall?

(Testimony of Dr. William A. Swim.)

A. Yes; that I can recall.

Q. This is at pages 141 and 142. Referring, now, to certain testimony by Dr. Macdonald—do you know Dr. Macdonald here locally?

A. I think I have met him.

Q. Referring to certain testimony by Dr. Ian Macdonald, appearing at page 142 of this transcript, a portion of which testimony was referred to you by Mr. Elson, there is a statement that there must be a certain amount of circulating estrogen, [684] over a long period of years, in a woman's life, within herself, in order that breast cancer may develop. You have mentioned a period of ten years. On that basis, you would not disagree with Dr. Macdonald, is that not correct?

Mr. Elson: On what basis?

Q. (By Mr. Danielson): Do you disagree with Dr. Macdonald in his statement that there must be a certain amount of circulating estrogen, over a long period of years, in a woman's life, within herself, in order that breast cancer may develop?

A. I would not agree with that statement.

Q. Yet the shortest period of years in which the estrogen has been present and in which you have seen such cancer was ten years, is that not correct?

A. That is right, sir, if I understand your question.

Q. Will you explain that?

A. Yes. I understood the ten years applied to when the party was devoid of estrogenic material, before she developed a malignancy of the breast.

(Testimony of Dr. William A. Swim.)

That was my understanding of your earlier question.

Q. And that was the correct meaning of your answer then? A. Yes.

Q. Was this ten years past the menopause?

A. Yes; that is right. [685]

Q. In other words, this woman had gone through a menopause? A. Yes.

Q. And prior to that she had had her normal supply of estrogen, is that not correct?

A. Yes, sir.

Q. Which probably had endured for 10 years?

A. Yes; more than 10 years.

Q. Which would be, in effect, stating that you have never seen cancer of the breast in a woman who did not have her natural supply of estrogen for at least a long period of years?

A. I think that is correct; yes.

Q. Doctor, are you at all familiar with Dr. Charles Huggins, of Chicago, his writings?

A. I know who he is. The first time I really knew anything about Dr. Huggins was in connection with his researches for cancer.

Q. That is, the blood test? A. Yes.

Q. You are not particularly familiar with his work, then? A. No; I am not.

Q. Doctor, are you familiar personally or by reputation with Dr. Elmer Belt here in Los Angeles?

A. Both.

Q. Do you consider him to be an authority in his field?

(Testimony of Dr. William A. Swim.)

A. Well, I never accept any medical man as an authority anywhere.

Q. Do you consider him to be an eminent physician in his field, Doctor? A. Yes.

Q. Did I understand you to say you are not certain whether you know Dr. Macdonald either personally or otherwise?

A. I am not sure that I do.

Q. How about Dr. Samuel Glass in Beverly Hills?

A. No; I don't know Dr. Glass.

Q. Doctor, would you prescribe estrogen to a woman suffering from a cancer of the uterus or cervix? A. If she needed it.

Q. A pre-menstrual woman, before the menopause.

A. I might do that if I felt that she had symptoms that required it.

Q. Regardless of the cancer, is that correct?

A. Of course, "menopause" there must be defined.

Q. Probably I am inadequately experienced to define it to that point. I mean at the time when she is still producing her own supply of estrogen. [687]

A. Well, if she is producing her own supply of estrogen, I, naturally, would not prescribe it. But it wouldn't hurt her.

Q. But you wouldn't prescribe it. A. No.

Q. Would you prescribe testosterone for a man with cancer of the prostate?

A. If he needed it.

(Testimony of Dr. William A. Swim.)

Q. How would you determine whether he needed it, Doctor?

A. If he had the middle-aged symptoms.

Q. You would do that strictly on the basis of the symptomatology, is that correct? A. Yes.

Q. Without any research to determine whether he was producing testosterones?

A. Yes; that is correct.

Mr. Danielson: Thank you very much. That is all.

Mr. Elson: That is all.

* * *

Mr. Elson: We will call Mr. Parkinson.

ALLEN H. PARKINSON

a witness for the defendants, being first duly sworn, testified as follows:

The Clerk: Which case is this?

* * *

Direct Examination

By Mr. Elson:

Q. Mr. Parkinson, you are the defendant in case No. 20,642? A. Yes, sir.

Q. You are the Allen H. Parkinson doing business as the Hudson Products Company?

A. Yes, sir.

Q. In count 1, it is alleged that you shipped certain tablets of testosterone, methyl testosterone, 10 milligrams, to a Robert Downing in Altoona,

(Testimony of Allen H. Parkinson.)

Pennsylvania, and accompanying that was a small circular, "The Male Hormone."

Mr. Neukom: Maybe your Honor can follow this better if we have this stipulation before the court——

* * *

The Court: For the purposes at hand, I have made what I believe is a sufficient examination of the stipulation. You may proceed. [695]

* * *

Q. Mr. Parkinson, will you take the stand again?

On June 24, 1949, did you go to Dr. Belt's office on Wilshire Boulevard? A. Yes, sir.

Q. Did you see anyone there? A. Yes, sir.

Q. About what time did you go there?

A. 10:00 a.m.

Q. Will you state whom you saw, what you did, and what conversations you had?

A. Yes, sir. At 10:00 a.m. on June 24th, I walked into Dr. Belt's office on Wilshire Boulevard, asked the receptionist if I could see one of the doctors. She referred me to a Dr. Ebert. Dr. Ebert asked me what I was there for [696] and I told him I would like some testosterone. He says, "Have you ever taken it before?" I says, "Yes; two years ago in Salt Lake City;" that a Dr. Openshaw prescribed some.

* * *

Q. (By Mr. Elson): Now, go ahead. What was the last statement made?

A. I walked into Dr. Ebert's office and I mentioned I would like some testosterone. He asked me

(Testimony of Allen H. Parkinson.)

if I had ever taken testosterone before. I said, "Yes; in Salt Lake City about two years ago," that Dr. Openshaw had given me some.

I mentioned I had had trouble with diminishing of the testicles and penis. And he said, "Are you taking it right now?" and I said "No," but that I continued taking it at frequent intervals because it has a tonic effect and makes me feel better. He said, "Would a 50 milligram shot of testosterone propionate be satisfactory?" And I said "Yes." I was then ushered into another room. In a few seconds, a laboratory assistant came in and took a blood sample. Then he went out of the room and Dr. Belt came in and gave me a brief rectal examination and went out of the room. Then another laboratory technician came in and injected me with a 50-milligram shot of testosterone propionate. [699]

The Court: How did you know?

The Witness: Dr. Ebert said it would be a 50-milligram shot of testosterone propionate. He left the room and then Dr. Belt put his head in the door and said, "What do you want on your prescription? How many tablets would you like on your prescription?" I mentioned that I would like 100 10-milligram tablets, or linguets—pardon me—of methyl testosterone. He said all right and then he had me urinate in three glasses. Then he asked me, "How do you take these, Allen?" I said, "I take three or four a day and then maybe I lay off three or four days, depending how I feel, and then I resume."

(Testimony of Allen H. Parkinson.)

He said all right. "What did the Doctor in Salt Lake City charge you?" And I said, "$5.00." And he said, "All right. Pay the girl $5.00 on your way out."

Q. (By Mr. Elson): Did he write out what purported to be a prescription at that time?

A. Yes, sir.

Q. I show you here what purports to be a prescription, on the prescription pad of Elmer Belt, Urologic Group. Is that the prescription that was written out? A. Yes, sir.

Q. Was that done in your presence?

A. No. He stepped out of the room to write it out but he handed it back to me. [700]

Q. Did you pay the girl $5.00?

A. Yes, sir.

Q. And did you get a receipt for it?

A. Yes, sir.

Q. Is this the receipt that you received?

A. Yes, sir.

Mr. Elson: I offer in evidence the prescription referred to by the witness.

The Clerk: Defendants' Exhibit F in evidence.

Mr. Elson: And I offer as the next exhibit in order the paper referred to by the witness as a receipt.

The Clerk: Defendants' Exhibit G in evidence.

Q. (By Mr. Elson): Mr. Parkinson, did you, on June 30, 1949, call at the offices of a Dr. E. A. Gummig in Pasadena? A. Yes, sir.

Q. About what time of the day?

(Testimony of Allen H. Parkinson.)

* * *

Mr. Danielson: We will object, your Honor, to any testimony as to statements of, or acts by these doctors who have never been before this court. [703]

* * *

The Court: Well, this witness is a defendant in the case and naturally he is looking for every bit of evidence that he may consider in his defense. I think I should hear it.

Q. (By Mr. Elson): Now, Mr. Parkinson, did you call at the office of Dr. E. A. Gummig in Pasadena on June 30, 1949? A. Yes, sir.

Q. At 416 First Trust Building?

A. Yes, sir.

The Court: What is that name?

Mr. Elson: E. A. Gummig.

The Court: In Pasadena. When?

Mr. Elson: June 30th.

The Court: Yes, go ahead.

Q. (By Mr. Elson): Will you state what happened when you called at that office, without, however, telling us anything that the doctor told you?

* * *

Mr. Neukom: All right. We will withdraw our objection.

The Court: I will hear this, to this extent: The witness may testify that from these several, various doctors, naming them, he obtained a prescription or got an administration of testosterone, without a physical examination, or if there was a physical examination, he may describe that.

(Testimony of Allen H. Parkinson.)

Mr. Elson: All right.

Q. You called on a doctor at that address?

A. Yes, sir.

Q. Did you receive a prescription for Metandren Linguets?

A. Yes, sir, 100 tablets of methyl testosterone linguets.

Q. I show you a prescription on the prescription pad of E. A. Gummig, and ask you if that is the prescription that you received.

A. Yes, sir, it is.

Q. At any time during your visit at the doctor's office, did he lay his hands on you?

A. No, sir.

Mr. Elson: I offer this as Defendants' Exhibit next in [709] order.

The Clerk: Defendants' Exhibit H in evidence.)

(The document referred to was marked Defendants' Exhibit H and received in evidence.)

Mr. Neukom: Our objection is as I previously stated.

The Court: The objection will be noted in the record.

Q. (By Mr. Elson): By the way, what was the approximate total length of time that you were in Dr. Belt's office?

A. Not over 10 minutes.

Q. What was the approximate length of time that you were in Dr. Gummig's office?

A. Not over one minute?

Mr. Elson: Cross-examine.

(Testimony of Allen H. Parkinson.)

Cross-Examination

By Mr. Danielson:

Q. Now, who was the first doctor you saw in Dr. Belt's offices, Mr. Parkinson? A. Dr. Ebiert.

Q. And precisely, what did you say to him?

A. I told him I would like some testosterone.

Q. Did you tell him you needed any testosterone?

A. I told him I would like some.

Q. What else did you tell him?

A. And he asked me if I had taken testosterone before. I said, "Yes, sir, approximately two years ago, a Dr. Openshaw in Salt Lake City administered some testosterone to me for receding of the testicles and penis," and it helped that condition and I continued taking it off and on because of the tonic effect.

Then he asked me if I had any children. I told him two. And if I was married, my age and my address. And I told him I would like a shot and he said a 50 milligram shot of testosterone propionate, and then I was ushered in this other room.

Q. And wasn't it true that Dr. Openshaw had so treated you? A. No, it was not.

Q. You were lying at that time, were you not, Mr. Parkinson? A. Yes, sir.

Q. You sell testosterone, do you not, Mr. Parkinson? A. Yes, sir.

Q. You have been selling it for some time, have you not? A. Yes, sir.

Q. You actually did not need any testosterone, did you?

(Testimony of Allen H. Parkinson.)

A. No. The shot did me no good whatsoever one way or the other.

Q. At least that is your opinion?

A. That is my opinion.

Q. You are not a doctor, are you?

A. No, sir.

Q. Are you a pharmacist? A. No, sir.

Q. You really don't know what happened to you as a result of the testosterone propionate, do you?

A. All I know, it had no effects on me whatsoever.

Q. All you know is you don't know what happened to you whatsoever?

A. No. I had no ill effects.

Q. Precisely, what samples were taken from you at Dr. Belt's office?

A. A blood sample and three urine tests.

Q. A blood sample was taken and three urine samples, is that correct? A. Yes.

Q. What was your purpose in going to Dr. Belt's office.

A. After hearing his testimony in this courtroom, it was unbelievable to me that those tests had been made, that although I am not a pharmacist, I have consulted with other doctors on the efficaciousness or harmful effects of testosterone, including Dr. Glass, and I know that those tests, from the doctors I consulted with, are not made, and the general consensus of opinion is that testosterone is not [712] dangerous and I could not believe my ears when I

(Testimony of Allen H. Parkinson.)

heard Dr. Belt said that, and I wanted to prove it to my own satisfaction.

Q. Do you know what tests Dr. Belt made?

A. I do know this, I was only there 10 minutes and that an elaborate test could not be made on my blood and urine in that time. That is my personal opinion.

Q. But you did tell him you had been to see Dr. Openshaw before?

A. I told Dr. Ebiert that it was approximately two years before that and that the condition was corrected and that now I was taking it for a tonic effect, and also Dr. Belt examined my testicles and penis and said, "They look all right now," and I said, "They are."

Q. He said they looked all right.

A. Yes, sir.

Q. Are you sure that he did not say they were atrophied or too small?

A. No, sir. He said they looked all right. Those are his exact words.

Q. But you did tell him, anyway, that Dr. Openshaw had prescribed this testosterone to you before?

A. I told Dr. Ebiert that was two years before.

Q. Did you tell that to Dr. Belt?

A. No. Dr. Belt did not ask me.

Q. Then, Dr. Ebiert left the room, before you got the [713] shot of testosterone?

A. Yes, sir.

Q. And before you got the prescription?

A. Yes, sir.

(Testimony of Allen H. Parkinson.)

Q. You do not know whether he consulted with Dr. Belt or not, then, do you?

A. I have no idea.

Q. You did testify that Dr. Belt conducted a rectal examination, did you not? A. Yes, sir.

Q. He felt your prostate apparently, then?

A. Yes, sir.

Q. Again, what was your purpose in going to Dr. Belt's office? Was it not to see if you could trick him? A. No, sir.

Q. Did you want testosterone when you went in there, actually want it?

A. No, I went there to find out on the fact testified to, if it was true what he said.

Q. You weren't going in there in good faith for medical treatment, were you?

A. I was going there in good faith to see if Dr. Belt's office would do what he claimed.

Q. Were you going in good faith for medical treatment? A. No, sir. [714]

Q. Did you in good faith tell him your past medical history?

A. I was not asked for my past medical history.

Q. Did you tell him in good faith you had been to see Dr. Openshaw? A. No.

Q. In other words, you lied to him, then. Your purpose in going there was not for medical treatment, was it?

A. My purpose in going there was for information.

Q. Just answer my question. A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. And you think that the total time that you remained within Dr. Belt's office was not over 10 minutes? A. Yes, sir.

Q. Now, you went to Dr. Gummig in Pasadena, and you already had a prescription for a hundred tablets of methyl testosterone, didn't you.

A. Yes, sir.

Q. And you went for another prescription for a hundred tablets at his office, did you not?

A. Yes, sir.

Q. Did you go in there in good faith, Mr. Parkinson?

A. I was going in there in good faith, in this respect, I was going in there in good faith to find out if a general practitioner did make an examination, if he did feel that it [715] was necessary.

Q. Were you going there for medical treatment that you needed? A. No.

Q. Or that you even thought you needed?

A. No.

Q. You were going there, were you not, only to try to procure more evidence, is that correct?

A. I was going there to find out what the general practitioner thought.

Q. Just answer my question. Were you going there to try to procure some more evidence for the purpose of this specific testimony. A. Yes, sir.

Q. And that was the only reason you went to see Dr. Belt, was it not? A. Yes, sir.

Q. You were trying to manufacture evidence, was that not correct? Just answer the question.

(Testimony of Allen H. Parkinson.)

A. Yes, sir.

Q. How old are you, Mr. Parkinson?

A. Thirty years old.

Q. When were you born?

A. January 26, 1919.

Q. You are married, are you? [716]

A. Yes, sir.

Q. Did you mention anything of that sort to Dr. Ebiert?

A. Dr. Ebiert asked me first——

Q. What address did you give Dr. Ebiert?

A. 341 Harding Street—G Street, pardon me, Salt Lake City, Utah, which was my address at that time two years ago.

Q. But it is not your address today?

A. No, sir.

* * *

Q. (By Mr. Danielson): Your address as of June 24, 1949, was what?

A. 341 Harding Street, Long Beach, California.

Q. And what address did you give to Dr. Belt?

A. 341 G Street, Salt Lake City, Utah.

Q. Was that your correct address?

A. No, sir.

Q. As a matter of fact, you were giving him a false address, were you not? A. Yes, sir. [717]

Q. And why did you give him a false address?

A. For the simple reason that I would be asked why I did not go to my local physician, which would——

(Testimony of Allen H. Parkinson.)

Q. Certainly embarrass you, would it not, Mr. Parkinson?

A. Yes, sir—not quite embarrass me, but I wouldn't have what I went there for.

Q. You did not need any prescription for testosterone, did you? A. No.

Q. You sell it? A. Yes, sir.

Q. You buy it wholesale, you can buy it wholesale? A. I manufacture it.

Q. You even manufacture it? A. Yes, sir.

Q. As well as evidence, is that correct?

A. I beg your pardon? [718]

* * *

Q. You, then, cannot only buy it wholesale, you can get it lower than wholesale, you make it?

A. Yes, sir.

Q. And you could have bought it from Mr. Clemens without a prescription, couldn't you.

A. I could buy it at quite a few drugstores or go to a doctor and ask for a prescription.

Q. You could have bought it from Mr. Clemens, without a prescription? A. Yes, sir.

Q. As well as from yourself? A. Yes, sir.

Q. The entire purpose of this entire journey, little foray of yours, was merely in bad faith to get prescriptions from doctors?

* * *

A. To determine the truth.

Q. To in bad faith, get prescriptions from doctors for testosterone, isn't that a fact?

(Testimony of Allen H. Parkinson.)

A. I was not in bad faith.

Q. Did you need the prescriptions?

A. No, sir. [719]

Q. But you went to them?

A. But I needed it to find out the truth.

Q. Now, did you tell Dr. Belt or any representative of his office that you had been taking testosterone over a period of about two years?

A. As I said before, approximately two years ago, that Dr. Openshaw had administered some testosterone to me and that off and on I had taken it, which is true, because it made me feel better.

Q. Now, did you tell them that Dr. Openshaw had been treating you with about 50 milligrams a week of testosterone? A. No, sir.

Q. Or what dosage?

A. No, sir. That suggestion came from Dr. Ebiert.

Q. What dosage did you tell them that you received? A. He did not ask me.

Q. What type of testosterone did you tell him you had been receiving?

A. He did not ask me that. He said, "Would you like a 50 milligram shot of testosterone propionate?"

* * *

Q. (By Mr. Danielson): What type of testosterone did you tell him you had been taking? [720]

A. I did not tell him. I said I had been taking testosterone, that was all.

Q. Didn't you tell him you had been taking testosterone propionate or Neo-Hombreol?

(Testimony of Allen H. Parkinson.)

A. No, sir.

Q. Did you tell him you had been taking testosterone intra-muscularly? A. No, sir.

Q. Did you tell him you had been taking testosterone, these 10 milligram tablets or linquets to which you referred? A. No, sir.

Q. Did you tell him you had been taking them three times a day? A. I told Dr. Ebiert that.

Q. That you had been taking them three times a day?

A. No, sir. Three or four times a day.

Q. Three or four times a day. Did you tell Dr. Belt who referred you to his office.

A. No. I was not asked that.

Q. Did you not tell Dr. Belt or his representative that Dr. Openshaw had recommended that you visit his office in Los Angeles?

A. No. I did not say that.

Q. You did not say that?

A. I said Dr. Openshaw had treated me two years ago. [721]

Q. Just specifically, did you tell Dr. Belt or his representative that Dr. Openshaw had recommended that you visit his office during your stay in Los Angeles, for testosterone propionate or any other testosterone? A. No, sir.

Q. Or to renew his prescription?

A. No, sir.

Q. Did you tell him that you were staying in Los Angeles very long? A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. Where did you tell him you were going?

A. I told him I was passing through.

Q. Where did you say you were going?

A. On my way to San Francisco.

Q. Did you tell him that your testicles had begun to atrophy two years ago?

A. I told Dr. Ebiert, not Dr. Belt.

Q. You told one of them that your testicles had begun to atrophy two years ago?

A. I told them that they had been receding.

Q. Was that true? A. No, sir.

Q. That was a lie, too, is that correct?

A. Yes.

Q. And you told that lie to a doctor in what, in so [722] far as he was concerned, was an honest visit of a patient to a doctor for treatment, is that correct?

Mr. Elson: I object to that on the grounds it is improper cross-examination and it calls for a conclusion of the witness in so far as what the doctor might have thought.

Mr. Danielson: I believe that the question is proper.

The Court: I think it does call for a conclusion.

Mr. Danielson: Thank you. I will withdraw that.

Q. Did you tell the doctor that you were there without need—you were there only to procure some evidence for this trial? A. No, sir.

Q. Did you tell him that you were there for treatment?

(Testimony of Allen H. Parkinson.)

A. I told him I was there because I wanted some testosterone.

Q. You told him you needed some?

A. I told him I wanted some testosterone.

Q. You told him the reason you wanted it was for a tonic?

A. No. I told him I had used testosterone before.

Q. You told him you had taken it for a tonic effect? A. Yes, sir. That is true.

Q. You did not tell him anything that would lead him to believe that you did not need it for tonic effect?

A. No, sir, nor did I tell him I was suffering from [723] any ailments. I was not asking for it for that purpose.

Q. Did you tell him that you were there for any reason other than the usual patient-physician relationship?

A. No. I told him I wanted some testosterone.

Q. And at that time you told him that your testicles had begun to shrink?

A. Two years ago, but they were all right now, and Dr. Belt looked at me and said they were all right.

Q. But, nevertheless, you did not tell the truth about that physical condition?

A. You are right, sir.

Q. Did not Dr. Belt or his associate tell you that they could not give you testosterone without conducting a physical examination.

A. I was not told that.

(Testimony of Allen H. Parkinson.)

Q. Did they not tell you that they could not give you the testosterone without conducting this examination to assure themselves that the material would do you no harm?

A. No. They did not tell me that.

Q. Such an examination was carried out, however, was it not? A. Yes, sir.

Q. Just what examination was carried out, what portions of your body were examined?

A. Rectal. [724]

Q. Any other? A. No, sir.

Q. Did they examine your eyes?

A. No, sir.

Q. Did they hold a light up before your eyes in a manner that doctors do in a general examination? A. No, sir.

Q. Did they examine your ears and nose?

A. No, sir.

Q. Examine your throat? A. No, sir.

Q. Did they examine your neck, feel of your thyroid? A. No, sir.

Q. Did they thump your chest? A. No, sir.

Q. Or back? Did they take your blood pressure?

A. No, sir.

Q. Did they take your pulse? A. No, sir.

Q. Did they listen to your heart, with this head phone set that doctors use? A. No.

Q. Did they feel of your abdomen?

A. No, sir.

Q. Did they test your reflexes, hit you with a hammer [725] on the knee? A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. Did they examine your penis?

A. Yes, sir, and my testicles.

Q. They examined your testicles. Did he make an examination of your scrotum by feel?

A. Just a cursory examination, yes, sir.

Q. What examination?

A. Just a brief examination.

Q. As to whether it is cursory, let us leave that to experts, Mr Parkinson. A. Yes, sir.

Q. He then felt of your—he did examine your prostate, in the rectal examination?

A. Yes, sir.

Q. Did he make any comment at that time?

A. He said it was all right. He said he could feel no hardness, to use his exact words.

Q. Then, apparently he was looking for hardness, then, is that correct? A. Yes, sir.

Q. He did make urine tests? A. Yes, sir.

The Witness: He took my urine, let us put it that way. [726]

Q. (By Mr. Danielson): That is correct, he took your urine. And he also took blood samples?

A. Yes, sir, blood sample.

Q. (By the Court): Did you note how many cubic centimeters he took of blood?

A. I would say about 50, sir, but at best that would be rough.

Q. (By Mr. Danielson): Have you done any laboratory work, Mr. Parkinson? A. No, sir.

Q. Have you ever taken a blood sample?

A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. You are not a chemist? A. No, sir.

Q. Nor a biologist? A. No, sir.

Q. What has been your business, Mr. Parkinson?

A. Previous to going into this business, I was general sales manager of the Piuma Wine Company. Previous to that I was national sales manager of Mercury Record Corporation.

Q. Is that phonograph records?

A. Yes, sir.

Q. How long have you been in this business, Mr. Parkinson?

A. Approximately two years. [727]

Q. As a matter of fact, you would not know what 50 cubic centimeters looks like, would you?

A. Yes, sir.

Q. How much is 50 cubic centimeters?

A. Well, it would come approximately to there (indicating on water glass).

Mr. Elson: There, indicating about an inch or three-quarters of an inch from the bottom——

A. Yes, sir.

Q. ——of a water-glass? A. Yes, sir.

The Court: How many cubic centimeters are there to the ounce?

A. I don't know, sir. The reason why I am familiar with that particular one is that I happen to have a viol in my office with centimeters on it.

Q. (By Mr. Danielson): Have you ever been known as Hazen A. Parkinson, Mr. Parkinson?

A. Yes, sir.

Q. Or just plain Allan Hazen Parkinson?

(Testimony of Allen H. Parkinson.)

A. Yes, sir.

Q. Or Allan Parkinson? A. Yes, sir.

Q. You have lived in Salt Lake City, I see, is that correct? [728] A. Yes, sir.

Q. And you have at least either lived in or been in Las Vegas, Nevada, is that not correct?

A. Yes, sir.

Q. Have you ever been convicted of a felony, Mr. Parkinson? A. No, sir.

Q. Now, Mr. Parkinson, I see you have been here from time to time. I also notice that you weren't here on a couple of days. Did you happen to be here, by any chance, during Dr. Belt's testimony on July 5th, on Tuesday of this week?

A. No, sir.

Q. You remained absent, when Dr. Belt was here, is that correct? A. Yes, sir.

Q. You did show up in the afternoon, I believe, did you not? A. Yes, sir.

Q. Now, Mr. Parkinson, Dr. Belt testified (this appears on page 436 of the transcript, starting at line 20):

"Now, you mentioned the precautionary examinations which were given." This was a question to Dr. Belt. "Assume for a moment, Doctor, that the patient told you that he was referred by another doctor who gave him such drugs from time to time, would that change the procedure at all? [729]

"A. Well, if a patient comes to me referred by another physician, I always allow the other physician the benefit of whatever doubt that might exist

(Testimony of Allen H. Parkinson.)

in my mind and my tendency is to go on with the original treatment he has established until I can communicate with him and discuss the problem with him. It is possible that the patient may not tell me things that he has communicated to his other physician. It is possible that I may not see things in that patient that the other physician saw. So, in the first place, a generously disposed human being would not say right away, 'Oh, your doctor is doing the wrong thing. My goodness, this is the trouble.' But you would conform to the treatment until you had an opportunity for discussion and coming to a common understanding of that.''

Now, as a matter of fact, Mr. Parkinson, you told Dr. Belt that you had been referred by Dr. Openshaw, is that not correct?

A. No. I mentioned that two years ago I had been to Dr. Openshaw.

Q. And that you went back to him for the same purpose, to get some testosterone?

A. Yes, sir.

Q. Now did you give Dr. Belt Dr. Openshaw's address?

A. No, sir. At Salt Lake City, I gave Salt Lake City, but not the street address. [730]

Q. Did you give him Dr. Openshaw's name, I mean full name? A. Yes, Dr. Openshaw.

Q. You told Dr. Belt that you were going to San Francisco and were here only temporarily.

A. I told Dr. Ebiert.

Q. Dr. Ebiert? A. Yes, sir.

(Testimony of Allen H. Parkinson.)

Q. Who was in Dr. Belt's office, also, at that time? A. Yes, Dr. Belt's clinic.

Q. And who, so far as you know, could or at least had an opportunity to talk to Dr. Belt prior to the time that Dr. Belt saw you?

A. He could have.

Q. And how did you happen to go to Pasadena, Mr. Parkinson?

A. My brother lives in Altadena and I was driving through and stopped off at this place, and while I was there I stopped in Pasadena to pick up the prescription.

Q. Dr. Belt did not refer you to Dr. Gummig, did he?

A. No, sir, and I did not tell Dr. Gummig that he did.

Q. Did you tell Dr. Gummig that Dr. Openshaw had? A. No, sir.

Q. Dr. Belt said he would—in fact, he did give you a prescription which would carry you over for a time at least, [731] isn't that correct?

A. Quite a time.

Q. And your purpose in going to Dr. Gummig was identical with your purpose in going to Dr. Belt, is that correct? A. Yes, sir.

Q. And you say that this entire examination cost you but $5 at Dr. Belt's office?

A. Yes, sir.

Q. And that included the general physical?

Mr. Elson: No, no.

A. No, no. There was no general physical.

(Testimony of Allen H. Parkinson.)

Q. (By Mr. Danielson): Well, yes, the general physical, when he examined your body from head to foot?

A. He did not examine my body from head to foot.

Mr. Elson: The examinations to which he has testified?

Q. (By Mr. Danielson): The examinations to which you have testified? A. Yes, sir.

Q. And likewise, the urine samples and whatever analysis may have followed from it?

A. Yes.

Q. Likewise the blood sample and whatever analysis may have followed from that?

A. Yes, sir.

Q. It was $5, is that correct? [732]

A. Yes, sir.

Q. That was the total charge? A. Yes.

* * *

Q. (By Mr. Danielson): Mr. Parkinson, you say that you did not believe that Dr. Belt was telling the truth up here on the witness stand, is that correct?

A. I did not mean it quite that way. The truth, that is a rather broad statement. Put it this way, I did not think that he went through the procedure that he said on the stand.

Q. You don't feel that the procedures he has described here on the stand, then, would necessarily be carried out by him in practice, is that correct?

(Testimony of Allen H. Parkinson.)

A. Yes, sir.

Q. You heard the testimony I read to you from Dr. Belt's testimony to the effect that when a patient comes to his office, having been referred by some other doctor, he would go right along with the other doctor's previous treatment?

A. I did not state I had been referred by Dr. Openshaw. I stated I had been to Dr. Openshaw some two years before.

Q. (By Mr. Danielson): You have heard the testimony, that I have read to you, to the effect that Dr. Belt said that if a patient comes into his office on referral from another doctor, he would tend to go along with the first doctor's treatment until he had a chance to communicate with that doctor and reach an agreement with him?

A. Yes, sir.

Q. Would it surprise you to think that Dr. Belt may have made such a communication with Dr. Openshaw?

A. Well, I am neutral on it.

Q. Would you be surprised if he carried out that practice which he testified to?

A. I have no opinion on that.

Mr. Danielson: No further questions. [734]

Redirect Examination

By Mr. Elson:

Q. Just one question. On this day that you went up there, you had this examination at 10:00 o'clock in the morning, was it? A. Yes, sir.

(Testimony of Allen H. Parkinson.)

Q. Did you return to the court room that morning, after this examination?

A. I was here at 11:00 o'clock.

Mr. Elson: That is all.

Recross-Examination

By Mr. Danielson:

Q. Mr. Parkinson, did you ever go back to Dr. Belt for the results of your examination?

A. I never asked him for them.

Q. Did he ever offer them to you?

A. No, sir.

Q. Just for the sake of the record, are you the same Allen H. Parkinson who is a defendant in the case of United States vs. Allen H. Parkinson?

A. Yes, sir.

Mr. Danielson: Thank you. That is all.

* * *

ALLEN H. PARKINSON

a witness for the defendants, being heretofore duly sworn, resumed the stand and testified further as follows:

Recross-Examination

By Mr. Danielson:

Q. Mr. Parkinson, you testified that you saw Dr. Openshaw two years ago, is that correct?

A. Yes, sir.

Q. Have you seen him since that time?

A. Yes, sir.

(Testimony of Allen H. Parkinson.)

Q. Is it not true you saw him about four months ago, more or less, in Salt Lake City? Is that correct? A. No, sir.

Q. When was the last time you did see Dr. Openshaw?

A. I was on my way back East and saw him a little while ago.

Q. Do you mean during the latter part of June, possibly? A. Yes, sir.

Q. During the time this trial has been in session?

A. Yes, sir.

Q. Did you not, likewise, see him several months ago? A. No, sir.

Q. Who was present with you in Dr. Openshaw's office [736] when you did see him a few weeks ago the last time you saw him? A. My father.

Q. Had your father, to your knowledge, received treatment from Dr. Openshaw before?

A. In what respect?

Q. In any professional respect.

A. I think so but I couldn't say definitely.

* * *

Q. By Mr. Danielson: Did you invite or ask or request Dr. Openshaw to come to Los Angeles and appear as a witness in this case? A. Yes, sir.

Q. Did you see Dr. Openshaw before or after you saw Dr. Belt on June 24th? A. After.

Q. After you saw Dr. Belt? A. Yes, sir.

Q. Did you tell Dr. Openshaw you had seen Dr. Belt? A. No, sir.

(Testimony of Allen H. Parkinson.)

Q. Or did you tell Dr. Belt you were going to see Dr. Openshaw? A. No, sir.

Q. What treatment did Dr. Openshaw give you?

A. No treatment.

Q. Did you request any treatment of him?

A. No, sir.

Q. Your purpose in going to see him was merely to invite him to be a witness here, is that correct?

A. Yes, sir.

* * *

Mr. Elson: Mrs. Shinglman, please.

HANNAH SHINGLMAN

called as a witness for the defendants, being first duly sworn, testified as follows:

The Clerk: Will you state your full name?

The Witness: Hannah Shinglman.

The Clerk: How do you spell it?

The Witness: H-a-n-n-a-h S-h-i-n-g-l-m-a-n; 9250 Olympic Boulevard, Beverly Hills.

Direct Examination

By Mr. Elson:

Q. Mrs. Shinglman, on June 27th of [739] this year, did you go to the office of the Elmer Belt Urologic Group in Beverly Hills?

A. Yes, sir.

Q. Will you state, please, what you did and whom you saw. In other words what took place?

Mr. Neukom: Now, your Honor, we are going to object to this. [740]

* * *

(Testimony of Hannah Shinglman.)

The Court: Overruled.

Q. (By Mr. Elson): You had gotten to the office of the Elmer Belt Urologic Group in Beverly Hills. Now, will you state what happened, Mrs. Shinglman?

A. Yes. I walked into the office and asked to see Dr. Belt and the nurse told me he was only there on Tuesday and Thursday mornings. I decided to leave but, on thought, I decided to go back in again and ask to see another doctor. So she told me to wait, that Dr. Letourneau was in and would speak to me. And she asked me of what nature I had come there and I told her I wished to discuss my husband with the doctor, personally. So I waited for Dr. Letourneau and he came into the office and he asked me what he could do for me and I told him we had been here around six or eight months and that previous to this time my husband had not been feeling well for the last few years; that he had been very nervous and was very jumpy and irritable, and we figured he must be going through the male change, and that a doctor in Chicago had given him some shots, and that he had done so well that he had put him on tablets. And I showed him the bottle, and he had run out, and so he gave me a prescription for those [745] tablets. He told me, if I liked, perhaps my husband would like to come in for examination. I told him he was quite busy. And in the meantime he wrote out the prescription.

(Testimony of Hannah Shinglman.)

Q. Was that done in your presence?

A. Yes, sir.

Q. I show you here a prescription on the prescription pad of the Elmer Belt Urologic Group, to Mrs. Shinglman, June 27, 1949, for 100 Metandren Linguets, 25 milligrams, one daily, and signed "M. Letourneau, M. D." Is that the prescription you received at that time? A. Yes, sir

Mr. Elson: I offer this in evidence as the defendants' next exhibit in order.

Mr. Danielson: The same objection.

Mr. Elson: And you may cross-examine.

The Clerk: That will be Defendants' Exhibit I in evidence.

Cross-Examination

By Mr. Danielson:

Q. Did you say your name is Mrs. Hannah Shinglman? A. That is correct.

Q. Are you married? A. Yes, sir.

Q. Do you still have a husband?

A. Yes, sir. [746]

Q. And you are living with him, is that correct?

A. Yes, sir.

Q. What is your business, Mrs. Shinglman?

A. I am a housewife.

Q. Do you have any other business?

A. No, sir.

Q. Are you being paid for testifying here today? A. I don't know.

(Testimony of Hannah Shinglman.)

Q. What agreement do you have as to being paid to testify here today?

A. No agreement.

Q. Who invited you to testify?

A. Mr. Elson.

Q. You were at Dr. Belt's office on June 27th?

A. Yes, sir.

Q. And at whose instigation did you go there?

A. Mr. Elson's.

Q. You hadn't planned to go there until Mr. Elson suggested you do so? A. Correct.

Q. Where do you live?

A. 9250 Olympic Boulevard, Beverly Hills.

Q. Where is his office?

A. On Lasky Drive.

Q. That is about how far from where you live?

A. Approximately a mile or a mile and a half.

Q. Did you tell Dr. Letourneau that you were there solely at the instigation of Mr. Elson?

A. No, sir.

Q. You said you were there because you wanted some tablets for your husband? A. Yes, sir.

Q. As a matter of fact, does your husband use such tablets? A. Yes, sir; he does.

Q. And has he been using them for some time?

A. Yes, sir.

Q. And you did show Dr. Letourneau the bottle, the old prescription?

A. Yes, sir. This is the bottle I gave him.

Q. And you told Dr. Letourneau that your husband had been taking these as the result of the

(Testimony of Hannah Shinglman.)

treatment of some doctor in Chicago, on his suggestion? A. Yes, sir.

Q. And it was after that that Dr. Letourneau gave you the prescription? A. Yes, sir.

Q. And no charge for the prescription?

A. No, sir.

Q. Just for the sake of the record, this label on this [748] bottle says, "100 tablets Metandren, Ciba's, trade name for methyl testosterone; each tablet contains 25 milligrams of methyl testosterone." That is correct, is it? A. Yes, sir.

Q. Were you subpoenaed to appear here, Mrs. Shinglman? A. No, sir.

Q. Have you received any pay at all?

A. No, sir.

Q. Any pay for appearing here?

A. No, sir.

Q. Has any promise or offer been made to you for payment? A. No, sir.

Q. Do you appear frequently as a witness in cases of this type? A. No, sir.

Q. Have you ever appeared as a witness professionally? A. No, sir.

Q. This is your first professional trip as a witness, then, is that correct?

A. It depends on what you call "professional."

Q. You have no other purpose in being here, have you? A. No, sir.

Q. You told Dr. Letourneau that you were here temporarily, isn't that correct? [749]

A. No. I told him we had only been here six or eight months.

(Testimony of Hannah Shinglman.)

Q. Who referred you to Dr. Letourneau?

A. Nobody.

Q. You just dropped in off the street, did you? You had no reference? A. He didn't ask me.

Q. Did you tell him whether you had any reference? A. No, sir.

Q. I believe you testified, Mrs. Shinglman, that, after showing the doctor the bottle and telling him this background about the medicine having been used by your husband—you did testify, did you not, that you then asked him to please give you some more, that the bottle was running dry?

A. Yes, sir.

Q. And I believe you also said that the doctor suggested that you have your husband come in for examination, is that not correct?

A. If he liked.

Q. Of course, you couldn't force him to come in, is that correct? Isn't that correct?

A. I don't know.

Q. The doctor couldn't force him to come in for examination? That is correct, isn't it? [750]

A. I don't know. [751]

* * *

Mr. Elson: Mr. Parkinson.

## HAZEN S. PARKINSON

called as a witness on behalf of the defendants, being first duly sworn, testified as follows:

The Clerk: Your full name?

A. Hazen S. Parkinson.

(Testimony of Hazen S. Parkinson.)

Direct Examination

By Mr. Elson:

Q. Mr. Parkinson, will you please speak loudly so that we call all hear you? A. Yes, sir.

Q. Mr. Parkinson, are you the father of Allen H. Parkinson? A. Yes, sir.

Q. Defendant in one of these actions?

A. Yes, sir.

Q. Did you recently accompany your son on a trip to Chicago? A. Yes, sir.

Q. By automobile? A. Yes, sir.

Q. And you arrived in Chicago on what day?

A. The 29th of June, I think it was—the 26th of June. [753]

Q. What day of the week would that be?

Q. What? A. Sunday.

Q. Sunday. On the following day, Monday, which was the 27th, of course, did you go to the office of Dr. Norris J. Heckel? A. Yes, sir.

Q. About what time of day?

A. It was shortly after 1:00 o'clock.

Q. In the afternoon? A. Yes, sir.

Q. Did you go into the office? A. Yes, sir.

Q. All right now, will you state who you saw and what happened?

A. I met the nurse and asked if I could see Dr. Heckel.

Q. Speak a little louder.

A. I met the nurse, first, and she asked me

(Testimony of Hazen S. Parkinson.)

what I wanted and I told her I would like to see Dr. Heckel, if he was in.

She said, "Be seated just a moment." And she went back and I suppose seen Dr. Heckel and she told me to be seated and he would see me shortly.

Mr. Neukom: Now, your Honor, I want to object. Here [754] is Dr. Heckel, a busy urologist back in Chicago. Now, we knew about this, and we have letters from Dr. Heckel explaining all this to us. This has not been a surprise to the Government. [755]

* * *

The Court: I don't want to hear any of the evidence of this witness' experience, nor do I want to see the letters of Dr. Heckel. He was on the stand here, called for a purpose. He testified as to that. Then he went into, upon examination, cross-examination or otherwise, as to what the average doctor might do, and I don't know that he is any more competent to testify as to that than a layman. I did not attach much, if any, importance or credence to his views as to what an average practitioner might do, in prescribing or administering this medicine. I don't want to go any further into that. [760]

* * *

The Court: I don't care for it. There isn't any doubt but what you could make a showing that thousands of doctors prescribe what a patient asks for. Unquestionably, you can find doctors who

(Testimony of Hazen S. Parkinson.)

will commit criminal abortion. Sometimes doctors don't stick to their own code. I don't care for any more of that evidence because I am satisfied, in my own mind, that this could go on ad infinitum. So I think it would be well to withdraw this witness.

Mr. Elson: Your Honor, for the purpose of the record, may I make an offer of proof in these two instances?

The Court: Yes; surely.

Mr. Elson: It will take me a little time to do it but, if you will bear with me, I would like to do it. With reference to this witness, Mr. H. S. Parkinson, I offer to prove that, on June 27, 1949, he went to the office of Dr. Norris J. Heckel shortly after 1:00 o'clock p.m.; that he saw the nurse first and she asked him who he wanted to see [762] there and he said some of the fellows in the garage in the hotel where he was staying sent him; that she first took his name and his address in Chicago, told him to be seated and she would see the doctor; that she went to see the doctor and then he waited about five minutes, when she took him into a room, told him to be seated there and the doctor would be in; that he came in in about three or four minutes and shook hands with Mr. Parkinson. Mr. Parkinson introduced himself, told the Doctor that he wanted to get this refilled and handed him an empty bottle.

He told the Doctor he was leaving to go on a ship right away and wanted to have the prescrip-

(Testimony of Hazen S. Parkinson.)

tion refilled. The Doctor asked him how old he was and he said 65 years old. The Doctor asked Mr. Parkinson if he was married and he replied no. The Doctor asked what he was taking them for and Mr. Parkinson replied that he thought that they sort of tightened up his muscles and toned up his system. The doctor gave him a glass and told him to give him a urine sample. The doctor left the room and was gone about three minutes. The doctor said maybe he had better have an examination and he examined his rectum, which examination consumed not over 30 seconds. The doctor asked how many he wanted and Parkinson said he wanted the bottle filled. The doctor replied, "That will be expensive," and Parkinson said that he was going on a ship and didn't want to run out. That he was going on shuttle runs, [763] which would consume about a year, and "You know on a ship there are several staying in a room and, whenever you take a pill, some of the others will want one, too, and you have got to give it to them." The doctor then wrote out the prescription in Mr. Parkinson's presence and handed it to him, for 500 Metandren Linguets, 5 milligrams, directions, one a day. Parkinson paid him $5.00. The doctor asked Parkinson how many he took per day and Parkinson replied that he sometimes took two or three, depending upon how he felt. The doctor said, "Why don't you just take one?" and Parkinson said, "Well, I can just take one if you say so. You are the doctor." Then Dr. Heckel said, "You can take

(Testimony of Hazen S. Parkinson.)

one or two a day for a week or two and then drop back to one a day." Nothing was said to Mr. Parkinson by the doctor about that the taking of this product might affect his sterility or fertility or that, if any other men on the ship might take it, it might accelerate the growth of a cancer of the prostate or affect their fertility.

I also offer to prove that Mr. Parkinson called on several doctors, on the dates mentioned on certain prescriptions, throughout parts of Los Angeles County, and talked at random; that in each instance he went into the doctor's office, told the doctor that he wanted this same bottle, the one he used when he saw Dr. Heckel, refilled, and asked for a prescription; that in each instance he received a prescription for [764] these linguets and on no occasion was anything said to Mr. Parkinson about sterility or fertility or cancer of the prostate, nor did any of the doctors lay a hand on him, and he did not call on any doctor who turned him down on the request for a prescription.

The doctors that would be subject to Mr. Parkinson's testimony in that regard would be Dr. G. G. Ferbryck, M. D., 516 Professional Building, 117 East 8th Street, Long Beach, California, who wrote out a prescription for Metandren Linguets, one a.m. and p.m., and the date was June 29, 1949; Dr. Wayne P. Hanson, in the same building, on June 30, 1949, wrote out a prescription for 500 10-milligram Metandren Linguets, directions, one linguet daily; that he also called on Dr. George D. Stilson

(Testimony of Hazen S. Parkinson.)

and Dr. Milo Ellik, together in the same office, 511 Professional Building, 117 East 8th Street, Long Beach, on June 30, and received a prescription from Dr. Ellik for 500 Metandren Linguets, directions, as directed; that he called on Dr. Raymond W. Kelso on June 31, 1949, the doctor's address being 117 East 8th Street, Long Beach, who wrote out a prescription for 250 10-milligram Metandren Linguets, with directions, dissolve one on tongue each day; that he called on George B. Hanson, M. D., 716 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, received a prescription for 250 Metandren Linguets, 10 milligrams, directions, one per day; that he [765] called on Dr. H. F. Gramlich on June 30, 1949, address, 117 East 8th Street, Long Beach, and received a prescription for one bottle of Metandren Linguets, directions, as directed; that he called on Dr. P. W. Prince of the Bishop Clinic Staff, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 250 10-milligram Metandren Linguets, directions, I guess it is, one daily, dissolve in mouth; that he called on Dr. L. L. Wiltse, 714 Professional Building, 117 East 8th Street, Long Beach, on June 30, 1949, and received a prescription for 500 Metandren Linguets, directions, take as directed; that he called on Dr. Marvin R. Lauer, 829 East Compton Boulevard, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, use as directed; that he called on Dr. Francis J. Ort,

(Testimony of Hazen S. Parkinson.)

107 North Santa Fe Avenue, Compton, California, on July 2, 1949, and received a prescription for 500 Metandren Linguets, directions, two daily; that he called on Dr. L. C. Lowe, 706 South Hill Street, Los Angeles, on July 1, 1949, and obtained a prescription for 500 Metandren Linguets, 10 milligrams, directions, as directed; that he called on Dr. Glenn E. Jones, 403 West 8th Street, Los Angeles, on July 1, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, one or two per day; that he called upon Dr. R. L. Byron, 1015 Chapman Building, 756 South Broadway, [766] Los Angeles, on July 1, 1949, and received a prescription for 500 Metandren Linguets, 10 milligrams, directions, one as directed.

The Court: The offer of proof is refused. You may file those prescriptions. [767]

* * *

The Court: Exhibit J is received in evidence.

The Clerk: Exhibit J in evidence.

* * *

Q. (By Mr. Elson): Let's start from here. You got into the office and now will you state, please, what happened?

A. I asked the nurse for Dr. Heckel and she said, "Be seated a minute and I will go in and see the Doctor."

She returned in a minute or two and said, "Be seated," or "Stay seated and the Doctor will be back." In about three minutes she took me into

(Testimony of Hazen S. Parkinson.)

another room and said, "The Doctor will come in here." In about three minutes he came in. We shook hands and I introduced myself and told him what I wanted. I told him I wanted to get this bottle refilled——

Q. What a minute. Did you have a bottle with you? A. Yes, sir.

Q. I have a bottle with a label on it, "Metandren Linguets, 500," with some other writing on there. Is that the bottle that you presented at that time? [772] A. That is right.

Q. Go ahead, please.

A. And I showed him a prescription I had from Dr. Openshaw, that I had been taking by injection.

Q. For testosterone?

A. Yes; the same thing. I told him I was going on a ship and I was going to take them by mouth.

The Court: You showed him a prescription from some other doctor?

The Witness: Yes; Dr. Openshaw had given me a prescription to be given by injection, and he says, "When you get on the ship, you will need to take them by mouth," and I had the prescription to take them by mouth. [773]

And he said he had just been to Los Angeles on a trial and I says, "Well, what was wrong, was there anything wrong with them?"

And he said, "No," and he said, "There are some conditions where they might make a palpation of the prostate gland."

(Testimony of Hazen S. Parkinson.)

And I said, "Was there anything wrong with taking them, then, that is going to do me any danger? If there is, I don't want them."

He said, "Oh, no, I don't know as they will do you any damage, but we don't want them sold over the counter."

Q. (By Mr. Elson): Did the doctor examine you in any way? A. Yes.

Q. Tell me what he did.

A. He took the urine—he gave me a glass and told me to give him a urinal sample and he examined my prostate.

Q. He put his finger up your rectum?

A. Yes.

Q. And did he write this prescription in your presence? A. Yes.

Q. And was there anything said by the doctor to you on the subject of fertility or sterility?

A. No.

Q. Did you, in your discussion with the doctor, discuss rooming with other men on a ship? [774]

A. Yes.

Q. Will you tell us what the subject of the conversation was?

A. Well, when I told him I wanted the 500, he said, "That is quite a few." He said, "They are expensive, too."

I said, "Well, if you have ever been on a ship, there are three or four men to a room and every time you take a pill, someone else wants one."

He laughed. He said, "That is right." So he

(Testimony of Hazen S. Parkinson.)

made them at 500. He said, "How do you take them?"

I said, "I take one or two a day mostly and according to how I feel."

He said, "I will put down here 'one a day,' and take them the way you feel, the way you have taken them before."

I said, "Okay," and I said, "They won't do me any damage?" He said, "No."

Q. (By Mr. Elson): All right. Now, how long a time was consumed, approximately, from the time you walked into the doctor's office until the time you walked out with the prescription?

A. I would say five or six minutes.

Mr. Elson: Cross-examine.

I would like to offer this bottle into evidence.

Mr. Neukom: No objection.

Mr. Elson: As defendants' exhibit next in order. [775]

The Clerk: That will be Defendants' Exhibit K, the bottle.

(The article referred to was marked Defendants' Exhibit K and received in evidence.)

Mr. Elson: And these other prescriptions that were included in, let us say, my second offer of proof. Would you mark these for identification, Mr. Clerk, as one composite exhibit, with the receipts attached to the ones in which receipts were obtained?

The Court: Yes.

The Clerk: Yes. That will be Defendants' Ex-

(Testimony of Hazen S. Parkinson.)

hibit L, for identification, group of receipts. Those are receipts and prescriptions.

(The documents referred to were marked Defendants' Exhibit L for identification.)

Cross-Examination

By Mr. Danielson:

Q. How old are you, Mr. Parkinson?

A. Sixty-five.

Q. As a matter of fact, you told Dr. Heckel you were 72, didn't you?

A. No, I did not. I showed him my merchant marine card, that says 65 right on it. I handed him that (indicating card).

Q. Where were you born? [776]

A. Franklin, Idaho.

Q. Where? A. Franklin, Idaho.

Q. And when? A. April 1, 1884.

Q. Who referred you to Dr. Heckel?

A. I told him that a man in a garage at the hotel where we stayed did.

Q. Who actually referred you to Dr. Heckel?

A. Why, my son.

Q. That is Mr. Parkinson here——

A. Yes.

Q. ——a defendant in one of these cases?

A. Yes, sir.

Q. You say you arrived in Chicago about June 26th? A. Yes, sir.

Q. Where were you just prior to that time?

A. You mean the day before?

(Testimony of Hazen S. Parkinson.)

Q. Well, two or three days before, had you just come in from Salt Lake City?

A. No. I was in Long Beach.

Q. From Long Beach, you came in?

A. Yes.

Q. What was the purpose of your trip to Chicago?

A. To get a prescription from Dr. Heckel. [777]

Q. That was you entire purpose of your trip from Long Beach, from the Pacific Coast to the city of Chicago?

A. Yes, sir, that was my entire purpose.

Q. Sir? A. That was the entire purpose.

Q. Who paid your expenses on that trip?

A. My son.

Q. Again referring to Allan Parkinson, a defendant in one of these cases? A. Yes, sir.

Q. When did you see Dr. Openshaw last, Mr. Parkinson?

A. It would be on the 25th of June.

Q. That is at Salt Lake City? A. Yes, sir.

Q. On the 25th of June? A. Yes, sir.

Q. And your son was present at that time, is that correct? A. Yes, sir.

Q. Is that not correct?

A. Yes, that is right.

Q. Did you receive any testosterone from Dr. Openshaw at that time?

A. I received a prescription, but no——

Q. You received a prescription at that time?

A. Yes, sir.

(Testimony of Hazen S. Parkinson.)

Q. Is that the prescription you showed to Dr. Heckel at Chicago? A. That is right.

Q. As a matter of fact, had you been taking testosterone for a couple of years?

A. I had taken some my son had given me.

Q. Had you been receiving any such treatment from Dr. Openshaw at Salt Lake City?

A. No, sir.

Q. When had you last seen him prior to June 25th?

A. I think I was in Salt Lake last fall and I saw him.

Q. When you are in Salt Lake, he is your regular doctor, is that correct? A. That is right.

Q. Are you a sailor, Mr. Parkinson?

A. I belong to the Coast Guard. That is a sailor, yes.

Q. Well, are you active as such?

A. Not right now.

Q. How long has it been since you were an active sea-going sailor?

A. The last time I was on a ship was just before the strike. It would be in September, I believe it was '47.

Q. That is nearly two years ago? [779]

A. Yes, they had a strike, then, and I got off and I haven't been on since.

Q. Then, actually, you are not presently a sailor?

A. Yes, I am always a sailor.

Q. But you are not an active sailor, anymore?

A. I am not an active sailor anymore.

(Testimony of Hazen S. Parkinson.)

Q. But you did tell Dr. Heckel that you were?

A. No. I told him I was trying to go to sea.

Q. And you told Dr. Heckel that you were gone from this country for long periods of time?

A. Yes.

Q. As a matter of fact, you have not been gone from this country for almost two years?

A. That is right, but I told him I would be gone for long periods when I got on a ship.

Q. You likewise told Dr. Heckel that you wanted enough testosterone for a year, is that correct?

A. That is correct.

Q. And not only for yourself, but for such other sailors that might want a pill now and then?

A. That might want them, yes.

Q. As a matter of fact, if you wanted to, you could buy testosterone from your son, couldn't you?

A. Oh, yes, yes.

Q. Wholesale. Your only purpose in going to Chicago [780] was just to get this prescription?

A. That is right.

Q. You told Dr. Heckel, did you not, that your son's doctor had given you a prescription for methyl testosterone? A. That is right.

Q. And that you had been taking those under your doctor's orders for the past several years?

A. That is right.

Q. And this was not true?

A. Not several years. Maybe two years.

Q. And this was not true, was it?

A. No, sir.

(Testimony of Hazen S. Parkinson.)

Q. And when Dr. Heckel gave you the prescription, he told you, did he not, requested, advised you to report to your physician at regular intervals?

A. Absolutely not. I was going on a ship. I couldn't swim over.

Q. They usually have doctors on a ship, don't they, the Coast Guard?

A. No, he didn't tell me anything about my doctor.

Q. Specifically, did he advise you to report to your physician at regular intervals?

A. He did not. He did not.

Mr. Danielson: No further questions.

Mr. Elson: That is all. [781]

* * *

Mr. Elson: May it please the court, Mr. Neukom, Mr. Danielson and myself have had a little discussion during the recess and I think that we can cover the balance of the case of Mr. Parkinson by a stipulation.

* * *

Mr. Elson: Yes. (Continuing) In connection with the Parkinson case, No. 20642, Criminal, that the pamphlet entitled "The Male Hormone," Government's Exhibit 1-A in Count 1, 2-A in Count 2, 3-A in Count 3 and 4-A in Count 4—— [782]

* * *

Mr. Elson: (Continuing) This booklet entitled "Male Sex Hormone Therapy," published by Roche-Organon, Inc., was [783] used as the source of ma-

terial in the preparation of both of those, the pamphlets that I have referred to as exhibits in the case;——

Mr. Danielson: That Mr. Parkinson would so testify.

Mr. Elson: ——that Mr. Parkinson would so testify.

The Court: That pamphlets you refer to are "The Story of Hormones"——

Mr. Elson: Yes, that is one of them. There is a duplication here. For instance, I am looking at Government's Exhibit 1-A in Count 1, and here is he pamphlet, here is the full pamphlet itself, that is 1.

Now, in connection with this Exhibit 3-B in Count 3, which is entitled "The Story of Hormones," that those two pamphlets, that the booklet entitled "Male Sex Hormone Therapy," published by Roche-Organon, Inc., was used as a source of material in the preparation of both of those pamphlets, and that Mr. Allan Parkinson would so testify.

Mr. Danielson: The government will stipulate that Mr. Allan Parkinson would testify that the described pamphlet "Male Sex Hormone Therapy" was used by him as source of material in preparation of these pamphlets.

Mr. Elson: That is correct.

Mr. Danielson: That is agreeable to the government.

The Court: These pamphlets were prepared by Parkinson of Hudson Products Company? [784]

Mr. Elson: Yes.

The Court: Yes. I see.

Mr. Elson: There are just the two pamphlets. "The Male Hormone" pamphlet is the small one here.

The Court: Is this in evidence here?

Mr. Elson: No. It is not, but I am going to offer it.

Mr. Danielson: Exhibits 1-A, 2-A, 3-A and 4-A are identical pamphlets.

Mr. Elson: They are identical pamphlets.

And the government and the defendant Parkinson stipulate accordingly?

Mr. Danielson: The government will so stipulate.

Mr. Elson: And so does the defendant Parkinson, and I therefore now offer into evidence the book that I have just referred to, "Male Sex Hormone Therapy," published by Roche-Organon, Inc., as the defendant Parkinson's next exhibit in order.

The Clerk: What exhibit number would that be, Mr. Elson?

Mr. Elson: I don't know.

Mr. Sturzenacker: That would be "A" for Parkinson.

Mr. Danielson: It would be "A" for Parkinson.

Mr. Elson: Yes, that is right.

The Clerk: That is in Case No. 20642, Defendant's Exhibit A in evidence.

Mr. Elson: Just a moment. [785]

The defense in Case 20596, Criminal, and the defendant in Case No. 20642, Criminal, rest.

Mr. Neukom: That is in both the Clemens and Parkinson cases. [786]

* * *

JOHN R. WINCH

called as a witness by and on behalf of the plaintiff, having been first duly sworn, was examined and testified as follows in reguttal: [788]

The Clerk: Your full name?

A. John R. Winch.

Direct Examination

By Mr. Danielson:

Q. Mr. Winch, what is your occupation?

A. I am inspector of the Food and Drug Administration, stationed at Phoenix, Arizona.

Q. And were you so employed on or about November 1, 1947? A. I was.

Q. Now, in the course of your employment, on or about that date did you have occasion to receive a parcel from Martin A. Clemens or the M. A. Clemens Pharmacy, Los Angeles? A. I did.

Q. Did you make a record, if any, of the nature of that parcel that you received?

A. I did, at that time. I made the record on November 1st. I have it here. [789]

Q. You have such a record with you?

A. Yes.

Q. What does that record include, in general terms?

A. That is a record which is a collection report that we fill out for every sample. We fill out one such form for every sample that we obtain or collect.

Q. Is that recorded in the regular course of your business? A. It is.

(Testimony of John R. Winch.)

Q. As an official business? A. Yes, sir.

Q. Does that include the wrapping of the parcel?

A. That includes the labeling, marker, or other description of the parcel, how much it contains, what there is of it and what I do with it.

Mr. Elson: What count is this?

Mr. Danielson: This is count 1, Mr. Elson.

If your Honor please, the purpose of this inquiry is to establish precisely what labeling accompanied the shipments which are the subjects of the several counts of the information filed against Mr. Clemens and the El-O-Pathic Pharmacy. There has been testimony before the court by Mr. Clemens to the effect that in each of these shipments labeling in addition to that which has been made the subject of the stipulation was included with the shipments, such as brochures [790] from the manufactures.

Q. Mr. Winch, I show you Government's Exhibits 1 and 1-A, which are a label and a pamphlet, Exhibit 1-A being a pamphlet entitled "Male and Female Sex Hormones," and ask you if you recognize them. A. I do.

Q. Does your name or initials appear thereon?

A. I have written on them the sample number, the date that I received the sample, and my initials.

Q. Now, does that sample number compare with the numbers on the report that you have before you?

A. That does.

Q. Are the labelings which are reported on that collection report?

(Testimony of John R. Winch.)

A. They are the labeling which is described in that collection report.

Q. Now, do you recall receiving this shipment?

A. I do.

Q. What labeling did accompany the shipment?

A. The labeling that accompanied the shipment, the material consisted of one carton, the carton contained one circular entitled "The Male and Female Sex Hormones," and it also contained one unlabeled clear plastic container of five tablets. This was the label that was on the carton.

Q. You are referring to Government's Exhibit 1? [791]

A. Government's Exhibit 1 is the label that was on the carton as I received it.

Government's Exhibit 1-A is the circular that had been included with that carton.

Q. Now, Mr. Winch, were there any other labels or pamphlets or literature included in this shipment? A. There were none.

Q. I particularly refer your attention to Defendant's Exhibit D, a brochure entitled "Oral Androgenic Therapy," and ask you whether it or a similar brochure accompanied this shipment. A. No.

Q. I likewise invite your attention to Defendants' Exhibits "C" captioned "Oral Estrogen Therapy," and "A" entitled "Menformon Dosules," and ask you whether either of them or any copy of them accompanied this shipment. A. No.

Q. This collection report, No. 30046-K, was made

(Testimony of John R. Winch.)

by you as you say in the regular course of your business.

A. That is correct, on the same day on which I received the carton through the mail.

Q. And you knew it to be accurate and correct at that time? A. That is right. [792]

* * *

The Court: I suggest this is merely the formal report submitted to this officer's superior as to his conduct and the happenings at that time and place.

Mr. Neukom: That is right.

Mr. Danielson: That is what it is, is it, Mr. Witness?

The Witness: Yes. I have a copy of it.

Mr. Elson: No, there isn't anything in that report or any of the documents that I have looked at, your Honor—it is a typical agent's report.

The Court: Well, to round out the record, let it go in as an exhibit.

Q. (By Mr. Danielson): Now, Mr. Winch, were you likewise employed in the same capacity on or about October 30, 1947? A. Yes.

Q. And did you on that date receive a package from the El-O-Pathic Pharmacy, Inc., Los Angeles, in Phoenix, Arizona?

A. I received the package that you are referring to on November 1st, according to my collection report, the document I filled out.

Q. That is from the El-O-Pathic Pharmacy?

A. From the El-O-Pathic Pharmacy, 1109½ North Western Avenue.

(Testimony of John R. Winch.)

Q. Los Angeles, California?

A. Yes, marked "Hollywood 27" here.

Q. Did you make a record of the labeling that accompanied that package? A. I did. [794]

Q. And what was the description of the contents of that package?

A. That package contained one carton, which contained one small envelope of five tablets, a circular and an envelope that had the return address of the El-O-Pathic Pharmacy. That is the contents.

Q. I invite your attention to Government's Exhibit 2, count 2, which is before you, and ask you if that label was included there.

A. This was the label that was on the carton that was contained in the package.

Q. I invite your attention to Government's Exhibit 2-A, before you, and ask you whether that label was included.

A. This is the circular that was included in that package.

Q. Were there any other labels or circulars included in that package? A. There were none.

Q. I particularly invite your attention to Defendants' Exhibits A, C and D, which are before you. Would you pick them up and show them to the court, if you please, Mr. Winch?

The Court. Yes.

The Witness: This is A. This one is D.

The Court: Yes.

The Witness: This one is C, your Honor.

The Court: Yes. [795]

(Testimony of John R. Winch.)

Q. (By Mr. Danielson): Were any of them or any copy of them included in this shipment?

A. No.

Mr. Danielson: Mr. Elson, are you willing to stipulate?

Mr. Neukom: To shorten the time.

Mr. Elson: On the others?

Mr. Neukom: Yes.

Mr. Elson: Sure.

Mr. Danielson: I believe, your Honor, counsel will now stipulate that as to these counts 3, 4, 5, 6, 7, 8 and 9, that the labeling received——

The Court: 3, 4?

Mr. Danielson: Up through 9, 9 inclusive.

The Court: Now, 3 was apparently handled by this witness; 4 by Brandenburg.

Mr. Neukom: We have him here.

Mr. Danielson: We have these witnesses here, your Honor. This is merely to shorten the time.

Mr. Elson: This is merely to shorten the time, because I know what they are going to testify to and there is no use of taking up the time.

The Court: Yes.

Mr. Neukom: As to all counts, your Honor.

The Court: 3, 4, 5, 6, down to and including 9?

Mr. Danielson: Including all of the counts, your Honor, [796] that would be up to and including 14.

The Court: Yes. Now, state your stipulation.

Mr. Danielson: Is that agreeable?

Mr. Neukom: I will make the stipulation:

The stipulation would be, your Honor, that as to

(Testimony of John R. Winch.)

all counts, either this witness or the other named government agents, or other individuals who are consignees, would testify, if called to the stand, that the only documents or articles they received in the various counts enumerated were those accompanying or set forth in the stipulation, and that they did not include Defendants' Exhibits C, D and A. That would be their testimony.

The Court: When you refer to the stipulation, you mean the one entered into as of June 15, 1949?

Mr. Danielson: In the Clemens case.

Mr. Neukom: Wait a minute. I will find out.

The Court: Yes, case No. 20596.

Mr. Neukom: June 15, 1949.

The Court: Yes, I get it. I think it is clear in the record.

Mr. Neukom: You so agree?

Mr. Elson: Yes, I do.

Mr. Neukom: As to both cases, Parkinson—oh, no; as to the Clemens case.

Mr. Elson: As to the Clemens case. [797]

Mr. Neukom: Yes.

Mr. Elson: Yes, I so agree.

Mr. Neukom: And as to counts 1 to 9, inclusive—and, if your Honor does not understand me, please stop me, because I am not embarrassed——

The Court: I hear you and understand you very well.

Mr. Neukom: As to counts 1 to 9, inclusive, the government will further stipulate that the products thereby obtained were the result of government

(Testimony of John R. Winch.)

agents operating in their official capacity writing in for the product, obtaining it in their official capacty, and that they did not actually use it or did not want to use it, but that they were just writing for it in the performance of their duty.

The Court: Yes.

Mr. Neukom: Is that satisfactory?

Mr. Elson: That is satisfactory.

Now, as to the Parkinson case.

Mr. Neukom: Now, in the other case, your Honor, the Parkinson case, we will make a similar stipulation in that case, only as to count 3——

Mr. Elson: 3 and 4, counts 3 and 4, the stipulation covering, however, only this: that the consignee in counts 3 and 4 were government agents.

Mr. Neukom: Just one.

Mr. Elson: Yes, but it was the same one in each count. [798]

Mr. Neukom: Yes.

Mr. Elson (Continuing): ——was a government agent who wrote in for the product, in count 3, from Seattle, and in count 4 from Seattle to Mr. Parkinson's place of business in Long Beach, ordering the shipment that was shipped; that the government agent ordered it for the purposes of obtaining evidence and in the performance of his duty as an officer, and that he did not use the product involved in either count for his own use or otherwise than as evidence in the case.

Mr. Neukom: That is right. [799]

Mr. Neukom: I don't think you have any questions, have you?

Mr. Elson: I have no questions. [800]

* * *

Rebuttal

Mr. Danielson: If your Honor please, in the interest of saving time, it has been agreed between counsel for the government and for the defendants as to what Dr. Heckel would testify to if he were recalled. With your permission, I would like to read that into the record.

It is stipulated and agreed that, if Dr. Norris J. Heckel were present and sworn as a witness to testify, and did so testify, he would testify that, on June 27, 1949, a [803] Mr. Parkinson came to his office in Chicago and stated that he had been referred to by a former patient. Parkinson said that he was 72 years of age, a sailor by occupation and gone from the country for long periods of time; that he was in Chicago as a transient; that his doctor in Salt Lake City had been giving him a prescription for methyl testosterone and that he had been taking this drug under his doctor's direction for the past several years; that he was leaving the country and needed about a year's supply of testosterone and requested a prescription for a year's supply. He showed Dr. Heckel a prescription for testosterone issued by another doctor. Dr. Heckel then made a physicial examination of Parkinson, which included a urine analysis and a rectal examination of the prostate and found no contraindication to the use

of testosterone; he found that Parkinson's prostate was of normal size, shape and consistency, with no evidence of prostatitis; and that he then renewed Parkinson's prescription for methyl testosterone linguets and advised him to report to his physician at regular intervals.

Mr. Elson: That is so stipulated, that, if Dr. Heckel were here, he would so testify.

Mr. Danielson: Thank you.

The Court: Very well.

Mr. Danielson: Dr. Terrill, please. [804]

ELWYN E. TERRILL, M.D.

called as a witness for the government in rebuttal, being first duly sworn, testified as follows:

The Clerk: Your full name?

The Witness: Dr. Elwyn E. Terrill (spelling same).

The Clerk: Which case is this?

Mr. Danielson: This is the El-O-Pathic and Parkinson; all of the cases. It is No. -596 and as it applies in the other case.

Mr. Elson: All right.

Direct Examination

By Mr. Danielson:

Q. Dr. Terrill, you are an M.D., is that correct?

A. Yes; I am.

Q. Where do your practice, Dr. Terrill?

A. 1401 South Hope Street, Los Angeles.

Q. From what schools were you graduated, Doctor? A. I graduated from Loma Linda.

(Testimony of Elwyn E. Terrill, M.D.)

Q. Is that where you received your M. D.?

A. Yes.

Q. In what year? A. In 1927.

Q. Did you have some connection with the College of Medical Evangelists?

A. That is the College of Medical Evangelists.

Q. Are you a member of any medical societies, Doctor?

A. I am a member of the Los Angeles County Medical Association, the State and the American Medical Association. I am a general practitioner and belong to that section of the County Medical Society and, also, the Academy of General Practice.

Q. Doctor, apparently you have been in general practice here for a little better than 20 years, is that correct? A. Yes, sir.

Q. Doctor, in the course of your practice, do you ever have occasion to prescribe testosterone?

A. I prescribe testosterone occasionally.

Q. Under what circumstances do you use testosterone?

A. Well, for a very limited field of conditions; usually a hypogonadism, if it is due to glandular origin.

Q. What precautions, if any, do you take prior to using testosterone?

A. I take a very careful history on all of my patients and always examine them completely.

Q. Does that include an examination of the prostate, Doctor?

(Testimony of Elwyn E. Terrill, M.D.)

A. Yes; in all male patients it does, especially if testosterone is to be considered.

Q. Why do you give this examination?

A. The examination of the prostate? [806]

Q. Yes, Doctor.

A. Well, because of the danger, as it is commonly believed today, of giving testosterone where there is any question of a carcinoma of the prostate.

Q. Doctor, you are a member of several medical societies and I presume you have discussions on medical subjects with other doctors from time to time, is that not correct? A. Yes, sir.

Q. Do you have an opinion as to whether the precautionary measures you have taken are general in the medical profession?

A. Among my circle of friends, I know they are.

Q. You do not know, among your circle of friends, of any promiscuous use of testosterone?

A. No; I do not know of any.

Q. That is the doctors among your friends?

A. Yes.

Mr. Danielson: No further examination. [807]

Cross-Examination

By Mr. Elson:

Q. Doctor, I am going to show you the Defendants' Exhibit L for identification, which consists of a number of prescriptions for linguets, and these prescriptions are by several doctors. They have been pinned together. I am going to ask you to look at those and tell me if you know or are ac-

(Testimony of Elwyn E. Terrill, M.D.)

quainted with any of the doctors whose names appear on there.

(The witness examines said exhibit.)

A. I recognize two names.

Q. Who are they, please?

A. Glenn Jones, 403 West Eighth Street.

Q. Long Beach?

A. No. Los Angeles. Isn't it Los Angeles?

Q. Yes, that is right.

A. And the other one,Marvin S. Lauer.

Q. And his address? A. Campton.

Q. Do you know of the Bishop Clinic staff at Long Beach?

A. No. I I know of it. I knew the name, but I don't know——

Q. Do you know Dr. Lauer, and who is the other?

A. Glenn Jones. I haven't seen Dr. Lauer for 20 years. [808]

Q. Now, if I told you that a man of the age of about 65 years called on each of the doctors whose names appear on the prescription pads that you have examined and told them that he wanted a refill of this bottle of Metandren Linguets, which is Defendants' Exhibit K, 500 Metandren Linguets, and that each one of those doctors wrote a prescription for this gentleman without laying a hand upon him, would that change your opinion in any respect as to the ordinary course of practice pursued by doctors in this locality in the use of testosterone?

A. May I ask you a question before I answer, so I get your question straight?

(Testimony of Elwyn E. Terrill, M.D.)

Q. Go ahead.

A. He came in and just asked for a refill on this prescription?

Q. That is correct.

A. And it was given without any examination?

Q. Without them laying a hand upon him.

A. I wouldn't think that was general practice in my community, at least not among my associates.

The Court: Where did you say you practiced?

A. 1401 South Hope Street, Los Angeles.

Q. (By Mr. Elson): Your address is 1401 South Hope? A. Yes, sir.

Q. And that is the same building, is it not, in which [809] the Food and Drug Administration's offices are located? A. Yes, it is.

Q. Do you do any work for the Food and Drug Administration?

A. I met the first man of that group I have ever met in my life just yesterday.

Mr. Elson: I haven't anything further.

Redirect Examination

By Mr. Danielson:

Q. Doctor, do you have any official connection with the Food and Drug Administration?

A. None whatever.

Q. And that building in which you are located, so far as you know, is a private building, is it not?

A. It was until the war I believe exclusively for doctors.

Mr. Danielson: No further questions. Thank you very much, Dr. Terrill.

* * *

Mr. Danielson: If the court please, in an effort to conserve time, again, it is agreeable between counsel for the government and counsel for the defense that the government could produce additional general practitioners who would [810] merely serve to corroborate the testimony of Dr. Terrill, and likewise, that the defense could produce additional general practitioners who would tend to corroborate their general practitioners, and we are willing to stipulate as to that fact and to eliminate further testimony of this nature.

The Court: I think that is very reasonable. [811]

* * *

Miss Nute, please.

JEANNETTE M. NUTE

called as a witness for the government in rebuttal, being first duly sworn, testified as follows:

The Clerk: Your full name?

The Witness: Jeannette M. Nute.

Direct Examination

By Mr. Danielson:

Q. Miss Nute, what is your occupation, please?

A. I am a registered nurse.

Q. Where are you employed? [814]

A. I am employed by Dr. Elmer Belt at 1893 Wilshire Boulevard, in Los Angeles.

(Testimony of Jeannette M. Nute.)

Q. Were you so employed on June 24, 1949?

A. Yes, sir.

Q. Miss Nute, I direct your attention to a Mr. Parkinson seated at the other table there, the second gentleman from the end. A. Yes, sir.

Q. Do you recognize him? A. Yes, sir.

Q. Did you have occasion to see him on June 24, 1949? A. Yes, sir; I did.

Q. And that was at the Belt Urologic Group, is that correct? A. Yes, sir.

Q. What were your duties there on that day?

A. I am a nurse receptionist for Dr. Belt and as such I take care of the patients as they come in to the office. I take their names down. If they are new patients, I place them in an office and, if they are regular patients, I direct them to the reception room. And, as the patients leave the office, I make appointments for them and give them the prescriptions ordered by the doctor and, of course, some of them make payments.

Q. Did you make any record of the time of arrival of [815] Mr. Parkinson at the clinic?

A. No. My assistant, Miss Kathleen O'Hare, or my associate, did.

Q. Was that made——

A. As Mr. Parkinson came in.

Q. That was made in the regular course of business there, is that correct? A. Yes, sir.

Q. Do you have that record?

A. Yes, sir; I do.

Q. What time was that arrival?

(Testimony of Jeannette M. Nute.)

A. Mr. Parkinson arrived at our office at 9:40, June 24th.

Q. 9:40 a.m.? A. Yes, sir.

Q. Do you have any record indicating how long he remained in your office? A. Yes, sir; I do.

Q. Will you tell us what records you have of the various times he was present in your office on the morning of June 24th?

A. As the patient comes into the office, a blue slip, such as this, is made out, indicating the time the patient comes in. Mr. Parkinson was a new patient. So, therefore, he was placed in one of the doctor's offices in the building, [816] which in this particular case was Dr. Ebert's office, which is No. 2. He was placed in Dr. Ebert's office at 9:45.

Q. How long did he remain there, according to your records?

A. According to our records, he remained there until 10 minutes after 10:00.

Q. And what was done with him then?

A. A history was taken between that time.

Q. Where did he go after 10:10, according to your records?

A. According to our records, he was taken to Room 15.

Q. How long did he remain there, according to your records?

A. According to our records, until 10 minutes of 11:00.

Q. Who would have seen him in Room 15, if you know?

(Testimony of Jeannette M. Nute.)

A. The technician, Mr. Joseph Hansel, I believe, instructed the patient to undress, and Dr. Belt then went in and gave a physical examination.

Q. Do you have any record of when he left the Group on completion of his visit that morning?

A. No, sir; I have not.

Q. But it would have been at 10:50 or subsequent to that time? A. Yes, sir. [817]

Mr. Danielson: No further questions.

Mr. Elson: May I see your record sheet?

The Witness: Yes, sir.

* * *

Mr. Danielson: Dr. Elmer Belt, please.

ELMER BELT, M.D.

a witness for the government in rebuttal, being previously duly sworn, was recalled and testified as follows:

The Court: You have been sworn.

Direct Examination

By Mr. Danielson:

Q. Dr. Belt, to clear up the record, there has been some confusion here as to the size of a normal prostate. You have had occasion to observe them on many occasions, is that right? A. Yes, sir.

Q. How large, Doctor, is a normal prostate in a normal male adult?

A. 19 grams. There are 30 grams in an ounce and you can figure about the size from that.

(Testimony of Elmer Belt, M.D.)

Q. This is a spheroid of what diameter, more or less? [818]

A. That is about the size that I am illustrating.

The Court: That is, a dollar?

The Witness: Oh, smaller than a dollar. I don't know how big a dollar looks to you, Judge. I brought some——

Q. (By Mr. Danielson): Do you have a prostate with you, Doctor?

A. Yes. If the Judge would like to see them, I have brought up samples of prostates that are normal in size and hypertrophied due to denign hypertrophy and hypertrophied due to cancer.

Q. Could we see a normal one, Doctor?

A. I don't know which jar contains the normal but they are stacked up there if you would like to see them.

Mr. Elson: You don't intend to introduce them into evidence, do you?

Mr. Danielson: No, Mr. Elson.

The Witness: This is a portion of a bladder and prostate which has been removed because of a cancer of the bladder. The cancer is where that section has been taken out. The prostate is the part you see from this point down, and on this side of the specimen only half of it is specimen because the specimen is cut exactly in two, which gives you the idea of the normal size of the prostate. This is a triangular area here, the top of which constitutes the floor of the bladder and the bottom of which is the pointed structure [819] below.

(Testimony of Elmer Belt, M.D.)

The Court: I have seen numerous illustrations of it.

The Witness: This is another specimen which shows the gland without having a slice through it, looking from the back. And, again, we have the trianugular structure, at the bottom of the bladder, of the prostate. Here it has a little window cut in it, from which this tumor growth was removed. From the anterior surface, the structure looks like that.

Q. (By Mr. Danielson): Doctor, what is this?

A. That is the tumor growth, the benign growth, which has been removed from the inside of the prostate.

The Court: I can see the patient died.

The Witness: Yes. That is an autopsy. [820]

* * *

The Court: Doctor, I would like to know just that part of the prostate which may be felt. It is complicated. All of it?

A. One feels the prostate from the posterior surface, the back surface. If you recall that triangle that had the V-shaped notch cut in it, in feeling the prostate, the finger passes over that surface. That surface would be covered by a thin membrane about half as thick as the thickness of your cheek, if you put one finger inside your mouth and the other outside. The rectal wall is about half that thickness. The [821] finger passing over that soft rectal wall detects the contour of the prostate which lies beneath it.

(Testimony of Elmer Belt, M.D.)

Now, in the normal structure, the prostate is quite soft and hard lumps which are occurring within it abnormally can be felt fairly well throughout the whole structure of the gland, but the part that presents itself to the palpating finger is the back surface of that triangle that you saw.

Q. (By the Court): Well, suppose a growth was on the opposite side?

A. One can still feel it, but less distinctly. And if you wish to distinguish the surface of the gland the growth is on, you have to put a hard object like a sound in the channel which passes through the gland. Then, those contours along the posterior surface can be felt against the sound and the structures which are abnormally present in the anterior surface are held away from the finger by the sound, and you can tell where they are in that way. A sound is a metal intrument passed through the channel. But, without the sound, the urethra collapses down to nothingness and one can feel the whole structure of the prostate fairly clearly.

The Court: Well, the prostate surrounds the urethra?

A. Yes. The urethra passes directly through the substance of the gland in about its middle portion. In this specimen, the slice is made down through the prostate in a medial sagital plane from before backward, so you can see the [822] course of a urethra passing through it, and you see also the relative proportion of the gland which lies behind and in front of the urethra, and you can see

(Testimony of Elmer Belt, M.D.)
that a finger pressing against this portion (indicating) will feel what is in here (indicating).

A finger pressing against the posterior portion will also detect what is present in the anterior.

Q. (By the Court): What is that projection out there (indicating)?

A. That is the vas deferens, which is carrying the sperm from the testicle to the seminal vesicle. In this specimen, the seminal vesicle has been disrected out, to show its exact position and the vas deferens is also shown and this kernel (indicating) is the prostate, and that area that you are looking at there is the region which is palpated most intimately by the examining finger. That (indicating) would be the posterior surface.

This (indicating) is the anterior, and you can see there (indicating) how the urethra passes directly through the prostate. That is the reason why a man becomes obstructed of urination, when the prostate enlarges, because it enlarges at the expense of that little space which is the urethra.

Q. (By the Court): Well, not altogether?

A. When an enlargement takes place, it takes place like that nodule of tissue is, it takes place in that manner and [823] the enlargement crowds in on the channel through which the patient must urinate.

Q. (By the Court): Well, in plain words, it is a general swelling of the prostate gland that enlarges both ways, inward, pressing on the urethra, and outward also, does it not?

(Testimony of Elmer Belt, M.D.)

A. That is right. But it is not a general swelling of the prostate. Enlargement is a specific thing that is happening. It is adenoma in the case of a benign hypertrophy, and an adenoma-carcenoma in the case of a malignant hypertrophy. And the benign prostate just crowds away the good prostatic tissue from the kernel of growing structure. In the case of a cancer, the cancer actually forms in the normal prostatic structure and it involves it as it advances.

The Court: Well, massage is used to reduce that enlargement in many instances, isn't it?

A. Prostatic massage has never, and does not now, reduce the size of a benign adenoma of the prostate. But if an inflammation in the prostate occurs and the prostate swells from accumulated products of inflammation, massage will sweep those products out and reduce the size of the prostate, but it doesn't reduce the size either of a cancer or a benign adenoma.

Q. (By the Court): Well, the benign adenoma is simply larger than the usual growth, isn't it? [824]

A. A benign adenoma is a growth, a nodular growth of a group of spheroids which occurs inside the prostate and produces a mass which blocks the channel.

Q. (By Mr. Danielson): Dr. Belt, I invite your attention to this gentleman sitting here, Mr. Parkinson. Now, you recognize him, do you?

A. Yes, indeed.

(Testimony of Elmer Belt, M.D.)

Q. Did you have occasion to treat Mr. Parkinson professionally on or about June 24, 1949?

A. Yes.

Q. Where was that examination, in your clinic here in Los Angeles? A. Yes, sir, in Room 15.

* * *

Mr. Danielson: I will rephrase that:

Q. Dr. Belt, did Mr. Parkinson tell you that he had been taking testosterone over a period of about two years?

A. Yes, sir. When I went into the room where Mr. Parkinson was, I reviewed the history which Dr. Satterlee in our [825] office had taken of him, briefly with him.

Q. And did he tell you that he had been taking testosterone propionate and Neo-Hombreol intramuscularly?

A. Yes, he said he had been receiving a weekly maintenance dose of 50 milligrams of testosterone Neo-Hombreol.

Mr. Elson: Just a minute. May I inquire—I notice the doctor is looking at something there—is that something that he wrote, or just what is it?

Q. (By Mr. Danielson): Doctor, you do have some notes there. Were they made in the usual course of your business? A. Yes.

Q. At or shortly after the time of the events which they purport to reflect?

A. At the moment.

Q. Were they made by you, or under your immediate supervision?

(Testimony of Elmer Belt, M.D.)

A. They were made under my immediate supervision and by me, both ways.

Mr. Elson: Well, then, if the court please, I have no objection of course to the doctor using the notes that he made for the purpose of refreshing his recollection. But, as to notes that were made by someone else, certainly that is hearsay. That is what the government has been complaining of here.

The Court: Well, if they are his business notes, made [826] in his presence at the time, he would know whether they were made accurately or not. I can't see hearsay in that.

Q. (By Mr. Danielson): Did Mr. Parkinson tell you, Doctor, that he had been taking 10 milligram tablets or linguets of testosterone three times daily?

A. He asked for such a prescription. I think he did not specifically state that he had been taking that. What he asked us for was these injections and he said he was going to San Francisco and he wished to have a maintenance dose of testosterone linguets to take with him.

* * *

Q. (By Mr. Danielson): Did Mr. Parkinson say who referred him to your office?

A. Yes. When I entered the room where Mr. Parkinson was, I asked him if Dr. Openshaw referred him to us and he said yes.

Q. Did he say why Dr. Openshaw had referred him to [827] you? A. Yes.

Q. Why was that?

(Testimony of Elmer Belt, M.D.)

A. He said that two years ago his testicles and penis had begun to atrophy and he became sexually impotent. He said that Dr. Openshaw of Salt Lake City had been treating him with a weekly maintenance dose of 50 milligrams of testosterone. He said that he had been away from Salt Lake City for three weeks and that his physician recommended that he come to us for this treatment. He said that he was leaving for San Francisco shortly.

Q. Did you make any general examination of Mr. Parkinson?

A. Yes, I made a complete examination of Mr. Parkinson, a complete general physical examination.

Q. What examination did you make, what steps did you take?

A. Mr. Parkinson took off his clothes and I examined him by first observing his general makeup, and his eyes, his pupils, his pharynx, his teeth, felt his thyroid, examined his thorax.

Q. By thorax, Doctor, you mean what?

A. Chest; I took his blood pressure, I determined his pulse rate and rhythm, I felt of his addomen, I looked at his extremities, I tapped his reflexes, I examined his external [828] genitalia, I put a finger in his rectum and examined his prostate.

Q. As a result of that, did you find any contraindication for the use of testosterone?

A. No. I found no contraindication.

(Testimony of Elmer Belt, M.D.)

Q. Did you take any samples from Mr. Parkinson?

A. I instructed my technician to take a specimen of his blood, and he had already been instructed to void in three glasses, which he did, and that material was examined.

Q. And what was your purpose in requesting the blood sample to be taken?

A. The patient told me that he intended to return, and I wanted to know whether or not the acid or alkaline phosphatase had changed.

Q. And the purpose of that test would be what?

A. To see whether or not there had been any maligant change in his prostate. It had been unheard of in a man of 30, but it might occur.

Q. Now, did you give a prescription for the testosterone to Mr. Parkinson? A. Yes, sir.

Q. Why did you do so, Doctor?

A. The patient told me that he was under the treatment of Dr. Openshaw of Salt Lake City, he said Dr. R. Openshaw, giving us the doctor's initial. I asked him that again, and asked him if Dr. Openshaw was giving him this material and he said he was.

And so I told Mr. Parkinson, before I began my examination, that the reason for doing it was that we examine people carefully who asked for this material or who were getting it, to be sure it wasn't doing them any harm. I did not wish, of course, to undermine Dr. Openshaw's authority with his patient. This man presented himself to me as a

(Testimony of Elmer Belt, M.D.)

transient actually under the care of another physician, and it would have been poor taste and poor policy and poor judgment on my part, as well as poor medicine, to interfere with the activities of his own physician.

Q. (By Mr. Danielson): Is that general professional practice?

A. Yes, with transients who are going to be in your office for only a short time, one would be extremely unwise in disputing the authority of his family doctor who is treating him constantly.

Q. In good professional medical practice, do you communicate such information to the patient's own doctor? A. Yes, at once.

Q. Did you do that in this case?

A. Yes. [830]

* * *

Q. (By Mr. Danielson): That is, you communicated with Dr. Openshaw at Salt Lake City, is that correct? A. Yes.

Q. Dr. Belt, I show you a copy of a letter which you have recently furnished to me. Is that a copy of the letter you furnished to Dr. Openshaw?

A. That is a carbon copy of it, yes.

Mr. Danielson: No further questions.

Cross-Examination

By Mr. Nelson:

Q. Do you have notes there, Doctor, from which you were reading?

(Testimony of Elmer Belt, M.D.)

A. Yes. Those are Dr. Satterlee's (indicating). Those are made by the doctor who talks to the patient.

Q. I just have a few questions here. I would like to use this, Doctor. What do you call this document you were looking at, Doctor?

A. That is the history.

Q. Now, on that history you say that was taken by Dr. Satterlee—— A. Yes.

Q. —— of your office? A. Yes.

Q. I would like to read into the record, if I may, the portion of it starting down here with [831] "Complaint."

If you want me to read the rest up at the top, I will.

Mr. Neukom: Read any part you want.

Mr. Elson: All right.

Q. Commencing with "Complaint," "Testosterone shots only."

What is that (indicating)?

A. History and physical.

Q. History and physical?

A. Wait a minute. Past history.

Q. What is this? A. H. P., past history.

Q. Oh, H. P.

A. I guess that is history and present ailment.

Q. H. P. I.? A. History of past illness.

Q. History of past illness. It reads as follows: Two years ago, this man's testicles and penis began to atrophy and he became sexually impotent. Dr. Openshaw of Salt Lake City has been treating him

(Testimony of Elmer Belt, M.D.)

with a weekly maintenance dose or 50 milligram testosterone Neo-Hombreol. He has been away from Salt Lake City for three weeks. His physician recommended that he come here for the same shots. He will be leaving here for San Francisco shortly. Wants oral prescription for Metandren 10 milligram tablets.

On the reverse side, what is this? [832]

A. Ear, nose and throat.

Q. What is this up here (indicating)?

A. Present illness, "P. I.," it looks like.

Q. And something here. "P. I." the doctor says indicates present illness. The nose, ears, eyes and throat, what is that?

A. Tonsillectomy and adenoidectomy.

Q. Tonsillectomy and adenoidectomy. And then over here, "No venereal diseases, no surgery, general health excellent; two children." What is that (indicating)?

A. "Daughter, age 13—and a boy aged 6 and a girl aged 4."

Q. Boy aged 6 and girl aged 4. What is that (indicating)? A. "Living and well."

Mr. Elson: Living and well.

Q. (By The Court): Doctor, would that weekly dose you referred to of 50 milligrams be taken all at one time?

A. 50 milligrans would, yes, by hypo, intramuscularly.

Q. Would that be testosterone propionate?

(Testimony of Elmer Belt, M.D.)

A. Propiniate, that would be testosterone propiniate in peanut oil.

Q. That was the shots that you gave him?

A. That is right.

Q. Isn't that a rather heavy dose? [833]

A. No. That is not very heavy for a weekly maintenance dose of testosterone.

Mr. Elson: Would your Honor bear with me a minute? I am looking at this.

The Court: Surely.

Mr. Danielson: Did your Honor have any further question on that?

Q. (By The Court): There is just one little item. The witness Parkinson testified that he paid you at your demand $5 for a treatment. How does that correspond with a similar treatment? For a new patient who would not come from another doctor? [834]

A. If this patient had not been referred to me from another doctor and if this were not a routine thing, a routine procedure, we would have charged him very much more for this entire procedure. Of course, $5.00 wasn't the total charge here. We explained to him that the laboratory test would be $6.50, which he said that he would like to have us bill him for to this false address that he gave us. This is a purely courtesy situation here. A patient comes in; he is being treated by another doctor in another city; we do our best to oblige both the doctor and the patient by carrying on the procedure that the doctor feels is indicated. I asked him what Dr.

(Testimony of Elmer Belt, M.D.)

Openshaw charged him for this treatment and he said $5.00. As a matter of fact, $5.00 is close to the cost of 50 milligrams of testosterone propionate. I don't know actually what the cost is to our office from the pharmacy but it is not under that. We charged him the same thing that his doctor charged him, as a matter of courtesy to that doctor, and we didn't charge him for the physical examination and for the urine analysis; nothing else except for the laboratory test.

Mr. Elson: I haven't any further questions.

Redirect Examination

By Mr. Danielson:

Q. Just one thing more, Doctor. What is the purpose of the peanut oil in that type of a weekly maintenance shot? [835]

A. It is simply a carrier for the medicine itself, so that it can be conveyed to the patient.

The Court: It makes it last longer in its distribution and effect, doesn't it?

The Witness: Yes; it absorbs slowly from the site.

Mr. Danielson: No further questions.

Mr. Elson: I haven't anything further.

The Court: That is all, Doctor.

Mr. Danielson: Dr. LeTourneau, please.

NORMAN HAROLD LeTOURNEAU, M.D.
a witness for the government in rebuttal, being first duly sworn, testified as follows:

The Clerk: Your full anme?

The Witness: Norman Harold LeTourneau, L-e-T-o-u-r-n-e-a-u.

Direct Examination

Q. (By Mr. Danielson): Dr. LeTourneau, are you an M.D.? A. I am.

Q. A medical doctor? A. Yes, sir.

Q. Where do you practice?

A. At 1893 Wilshire Boulevard.

Q. Are you a member of the Belt Urologic Group? A. That is correct. [836]

Q. Were you so employed on or about June 27, 1949? A. Yes; I was.

Q. Now, Dr. LeTourneau, I direct your attention to a lady sitting here in the front row of the spectators, with a large-brim blue hat on, with red trimming, and ask you if you recognize her.

A. I certainly do.

Q. Did you have any occasion to see her on or about June 27, 1949? A. I did.

Q. And where was that?

A. At 120 Lasky Drive; in the Beverly Hills office of the Elmer Belt Urologic Group.

Q. Doctor, what was the occasion of your seeing her—or do you remember her name?

A. Hannah Shinglman.

(Testimony of Norman Harold LeTourneau, M.D.)

Q. What was the occasion of your seeing Mrs. Shinglman on that day?

A. She came into the office of her own accord, as we thought, as a new patient.

Q. Will you speak louder, please?

A. She came into the office of her own accord and was, as we thought, a new patient, and she was put in a room as a new patient.

Q. Did you have any conversation with her yourself? [837] A. I did.

Q. What was the substance of that conversation, Doctor?

A. She told me that a Dr. Willard Shinglman, of Cicero, Illinois, was the brother of her husband; that Dr. Shinglman had directed her to our office and that Dr. Shinglman had been giving his brother tablets of, as she phrased it, testosterone linguets.

Q. And by his brother you mean her husband, is that right? A. That is correct.

Q. Will you continue, please?

A. I made a little note of the conversation, fortunately.

Q. Did you make the notes at that time?

A. At that time.

Q. In the regular course of your business?

A. Yes, sir.

Q. What was this conversation, Doctor?

A. Well, the part that I made a note of, I put down her husband's name as Sigmund Shinglman, who was under the care of Dr. Willard Shinglman, and, in parenthesis, Cicero—I have got Chicago but

(Testimony of Norman Harold LeTourneau, M.D.)

it should have been Illinois. "Dr. Shinglman has his brother on 25 milligrams of testosterone linguets (Metandren). She comes to our office for a [838] refill of the prescription. I advised her that she have Dr. Willard Shinglman write us a letter regarding the patient, explaining his findings and the need for the Metandren, and we would gladly provide a prescription for Metandren linguets." She said she would do this. I gave a prescription for 100 tablets of Metandren linguets.

Q. Doctor, did you make any charge for this prescription?

A. I did not. I did it as a courtesy, or I thought I was doing it as a courtesy to Dr. Willard Shinglman.

Q. As a professional courtesy, is that correct?

A. That is right.

Q. Doctor, did she show you any prescription or any bottle bearing a label at that time?

A. She did not.

Q. Did you see her husband at all?

A. I did not.

Q. Did you request that this husband appear?

A. I told her that she should bring him in for an examination.

Q. Did you say "should" or "would," Doctor?

A. Should.

Q. "S-h"? A. "S-h."

Q. And did she make any reply to that? [839]

A. I don't remember.

(Testimony of Norman Harold LeTourneau, M.D.)

Q. Did she say how long she had been in Los Angeles, Doctor, if you recall?

A. I believe she stated three or four months.

Q. Doctor, was there anyone else present, a nurse or anyone?

A. Not during our conversation. That was in my office.

Mr. Danielson: No further questions, Doctor. Thank you.

Cross-Examination

By Mr. Elson:

Q. Doctor, may I see your note there, please? I would like to read into the record, if I may, the notes from which the Doctor was reading, that he stated were made, I believe, at the time.

A. That is right.

Mr. Elson: "9250 Olympic Boulevard, Beverly Hills. (No appointment yet.) Mrs. Shinglman re her husband," and then the name under that, "Hannah," and over at the left-hand margin, "June 29, 1949."

"Her husband's name is Sigmund Shinglman, who is under care of Dr. Willard Shinglman, his brother, in Cicero, Chicago. Dr. Shinglman has his brother on 25 milligrams testosterone linguets, Metandren. She comes to our office [840] for refill of prescription. I advised her that she have Dr. Willard Shinglman write us a letter regarding patient, explaining his findings and the need for Metandren and we would gladly provide prescriptions for Me-

(Testimony of Norman Harold LeTourneau, M.D.)

tandren linguets. She stated she would do this. I gave prescription for 100 tablets Metandren linguets."

Q. Now, Doctor, I show you Defendants' Exhibit I, which is a prescription on the prescription pad of the Elmer Belt Urologic Group. Is that the prescription that you gave to her at that time?

A. That is correct.

Q. Doctor, isn't it true that linguets, Metandren linguets, are not manufactured in sizes of 25 milligrams? A. I believe it is.

Q. Metandren is, in fact, a tablet and not a liquid, is it not?

A. It is a trade name. It is called Metandren Linguets, Ciba's Preparation.

Q. But the name Metandren is the name of the tablets rather than linguets, it is not? [841]

* * *

The Witness: The name of the Ciba preparation is Metandren Linguets.

Q. (By Mr. Elson): Are you sure of that?

A. Yes.

Q. And the linguets come in 25 milligrams?

A. I believe they do.

Q. Are you sure?

A. I am not positive.

Q. What?

A. I have never prescribed it in larger than 10-milligram doses. So I am not positive of that dosage.

Mr. Elson: I have no further questions.

* * *

(Testimony of Norman Harold LeTourneau, M.D.)

Mr Danielson: Your Honor, the government rests.

Mr. Elson: The defense rests. [842]

The Clerk: In what cases?

Mr. Elson: In both cases, United States vs. El-O-Pathic Pharmacy, No. 20,596, Criminal, and United States vs. Allen H. Parkinson, No. 20,642, Criminal [843]

* * *

July 13, 1949, 10:00 o'Clock A.M.

The Clerk: No. 20642, U. S. A. v. Parkinson.

Mr. Elson: Ready.

Mr. Danielson: Ready for the plaintiff.

The Clerk: No. 20596, U. S. A. v. El-O-Pathic and Clemens.

Mr. Danielson: Ready for the Government.

Mr. Elson: Ready for the defendants.

* * *

The Court: As to cases 20596, 20642 and 20608, from the evidence and the weight of the evidence I am convinced, beyond a reasonable doubt, that the indiscriminate distribution or dispensation for use of the drugs Testosterone, Methyl-testosterone, Non-Crystalline Estrone and Alpha Estradiol carries not only a potential but an actual danger of injury to some persons. I am also convinced from the evidence that these drugs do not, other than within a restricted class of cases, produce many or any of the alleviatory and beneficial effects that the labeling given them by the defendants indicate and encourage readers to believe that they will generally produce.

I find, from the evidence and the stipulations between the defendants and the Government plaintiff, that the defendants introduced into interstate commerce misbranded drugs; [3]

Wherefore, I Find the defendant El-O-Pathic Pharmacy, Inc., and Martin A. Clemens Guilty of charges made in the Information in Case No. 20596, in Counts therein, 1 to 14, inclusive; and

I Find the defendant Allen H. Parkinson, trading as Hudson Products Company, Guilty of charges made in the Information in Case No. 20642, in Counts therein, 1 to 4, inclusive.

* * *

Now, it is my construction of those pamphlets, leaflets and circulars enclosed in the packages, by which delivery of sales were made, that they were designed to create a belief that many persons are deficient in their natural testosterone and that by supplementing it with the drug called under various names, a synthetic testosterone, that much benefit could be derived by the user. I do not mean this to convey the impression that I think the defendants intended any fraud. They may, so far as I know, have been acting in full belief of the merits of the drugs for the purposes they recommended them.

I don't think there is anything further that I need say in the cases. [4]

When will the defendants be ready for sentence?

Mr. Elson: So far as the defendants in the El-O-Pathic case and in the Parkinson case are concerned,

they are ready for sentence now, your Honor.

* * *

The Court: You spoke in regard to the Parkinson case, as well as the El-O-Pathic case?

Mr. Elson: Yes, the El-O-Pathic and the Parkinson case.

The Court: That covers all of them, then.

Mr. Elson: Yes, that is correct.

There is only this that I do want to say, in mitigation, your Honor, and that is that your Honor undoubtedly has in mind the fact that in the El-O-Pathic case, Counts 1 to 9, inclusive, were purchases by Government agents, and Counts 3 and 4 in the Parkinson case were likewise purchases by Government agents.

The Court: Very well. Does the Government have anything to say?

Mr. Danielson: If your Honor please, Mr. Roe of the Food and Drug Administration is present in court and we feel [5] that it is possible that your Honor would like to hear from him as to a little of the background of this case, some aspects that did not come out in trial.

The Court: I think not.

Mr. Danielson: Thank you.

* * *

The Court: Martin A. Clemens.

Defendant Martin A. Clemens: Yes, your Honor.

Mr. Danielson: If your Honor please, could I make one additional statement?

The Court: Yes.

Mr. Danielson: In the case of Martin A. Clemens and El-O-Pathic Pharmacy, we feel, your Honor, that because of the magnitude of this operation, the fact that here in yesterday's paper the ads continue, that there should be some substantial penalty imposed.

Mr. Elson: Well now, may I reply to that, please?

The Court: I think I shall reply to that, that so far as I know this is the first time that the defendant [6] Clemens or the El-O-Pathic Pharmacy has been before the court in this matter, and it would follow that the defendant had a right to assume himself innocent until the court passed on it. So that I wouldn't feel disposed to punish him for having carried on the business even though it is now found by the Court to be unlawful.

Mr. Danielson: I understand, your Honor. Thank you.

Mr. Elson: Your Honor has in mind, do you, that Clemens doing business as M. A. Clemens Pharmacy is charged in certain counts, and the El-O-Pathic Pharmacy, of which Clemens is the manager, is the subject of other counts; in other words, they are not included in the same counts?

The Court: That is something that I overlooked.

Mr. Elson: May I call your attention to this, that in Count 1, Clemens as an individual, doing business as Clemens Pharmacy, is the defendant charged; in Count 2 it is the El-O-Pathic Pharmacy or El-O-Pathic Pharmacy, Inc., that is charged, with Clemens of course the manager and director; in

Count 3 it is El-O-Pathic; in Count 4, it is Clemens, doing business as Clemens Pharmacy; so is Count 5; so is Count 6, and so is Count 7; in Count 8 it is El-O-Pathic Pharmacy; in Count 9, it is El-O-Pathic Pharmacy; in Count 10 it is Clemens, doing business as Clemens Pharmacy; in [7] Count 11 it is El-O-Pathic Pharmacy; in Count 12 it is El-O-Pathic; in Count 13 it is Clemens, doing business as Clemens Pharmacy; and in Count 14 it is El-O-Pathic Pharmacy.

Mr. Clemens just acquired the El-O-Pathic about 2 years ago.

The Court: That is 7 counts for Clemens and 7 counts for the El-O-Pathic.

Mr. Elson: I didn't count them.

The Court: I had overlooked that.

I Modify my Finding as to Guilt to conform with that statement of fact; that Mr. Clemens, defendant, is found Guilty in 7 Counts on the Information in case No. 20596.

Mr. Danielson: If your Honor please, I wish in this connection to point out to your Honor that in all of the counts in which the El-O-Pathic Pharmacy is charged, the charge is that El-O-Pathic, incorporated, organized and existing, and so forth, and Martin A. Clemens, an individual, "at the time hereinafter mentioned, the Manager and Director of said corporation," is the Mr. Clemens actually appearing in all counts.

Mr. Elson: That is true, but the reason that I was bringing that to the attention of the court was

so that there would not be any confusion that Clemens [8] Pharmacy and El-O-Pathic were involved in the same counts; in other words, one count will be El-O-Pathic in which Clemens is the director and manager, and there would be another count in which Clemens Pharmacy is the shipper.

Mr. Danielson: That is correct.

The Court: Now, Mr. Danielson, as I understand it now, of these 14 counts, 7 of them are chargeable against Clemens in his individual or in his business relation capacity and 7 are chargeable against the Corporation, El-O-Pathic Pharmacy, Inc.

Mr. Danielson: Well, that is not quite correct, your Honor. In the 7 counts charging the El-O-Pathic, Mr. Clemens as an individual is likewise charged. So, therefore, Mr. Clemens appears as an individual in all 14 counts. The corporation appears only in 7 counts, that is, the El-O-Pathic corporation.

The Court: Well, I am inclined to say that as to the counts involving the corporation, wherein it is found guilty, that Clemens was not acting in an individual capacity, that since the corporation is found guilty on these counts, that they shouldn't lie against an individual. That is my view of it.

Mr. Clemens, the El-O-Pathic Pharmacy, Inc., having been found guilty in 7 counts, It Is the Judgment and [9] Sentence of the Court, this being the first offense, that it pay a fine of One Hundred ($100.00) Dollars per count, a total of Seven Hundred ($700.00) Dollars; and you personally, being

found guilty, It Is the Judgment and Sentence of the Court that you pay a fine of ($100.00) Dollars for each of 7 counts, a total of Seven Hundred ($700.00) Dollars.

Mr. Elson: Now, your Honor, in connection with that, could we have a stay until Mr. Clemens can get to the bank?

The Court: Yes.

Mr. Danielson: Would your Honor kindly state which counts the fines apply to in each of these cases, in order that the Clerk can make the proper entry?

The Court: Yes, I should like to have counsel——

Mr. Elson: I can assist you on that.

The Court: Yes.

Mr. Elson: As to El-O-Pathic, that would be Count 2, Count 3, Count 8, Count 9, Count 11, Count 12 and Count 14; and as to Clemens, doing business as Clemens Pharmacy, it would be Count 1, Count 4, Count 5, Count 6, Count 7, Count 10 and Count 13.

Mr. Danielson: Thank you.

Then, Mr. Elson, you will stipulate that the Judgment applies to these particular counts named, is that correct, [10] as to each defendant?

Mr. Elson: Yes.

The Court: All right, the Court adopts those recited figures and the Judgments and Sentences so apply.

The Clerk: What about the stay, your Honor?

The Court: The execution of sentence will be stayed. How long do you want?

Mr. Elson: Let us say until tomorrow morning.

The Court: Tomorrow morning, July 14th, 1949, at 10:00 o'clock.

Now, Allen H. Parkinson, you have been found Guilty, on 4 counts. It Is the Judgment and Sentence of the Court that you pay a fine of One Hundred Dollars ($100.00) on each of the four counts 1, 2, 3 and 4, a total of Four Hundred ($400.00) Dollars. Are you prepared to pay that at this time?

Mr. Elson: Could we have a stay until tomorrow morning at 10:00 o'clock?

The Court: The same stay, until tomorrow morning at 10:00 o'clock for execution of sentence. [11]

* * *

Certificate

I hereby certify that I am a duly appointed, qualified and acting official court reporter of the United States District Court for the Southern District of California.

I further certify that the foregoing is a true and correct transcript of the proceedings had in the above-entitled cause on the date or dates specified therein, and that said transcript is a true and correct transcription of my stenographic notes.

Dated at Los Angeles, California, this 22nd day of July, A.D., 1949.

/s/ THOMAS B. GOODWILL,
Official Reporter.

[Endorsed]: Filed July 26, 1949.

[Title of District Court and Cause, No. 11,266-HW.]

and

[Title of District Court and Cause, No. 10,391-HW.]

REPORTER'S TRANSCRIPT
OF PROCEEDINGS

Los Angeles, California
Wednesday, March 22, 1950

Appearances:

For the Plaintiff:

ERNEST A. TOLIN, ESQ.,
United States Attorney, by
GEORGE E. DANIELSON, ESQ.,
Assistant United States Attorney.

For the Defendants:

EUGENE M. ELSON, ESQ.,
541 South Spring Street,
Los Angeles 13, California.

The Clerk: United States of America vs. El-O-Pathic Pharmacy, a corporation, et al., No. 10,266-HW Civil; and United States of America vs. Hudson Products Company, a corporation, et al., No. 10,391-HW Civil.

The Court: Was there any formal stipulation on file relative to this? It was not a consolidation of these two cases, but just a kind of gentleman's agreement?

Mr. Elson: No, that was not stipulated. They were not consolidated, but when we got up to argue them before Judge Cavanah, he asked us if there was anything that was identical between the two cases, and I think I am right, am I not——

Mr. Danielson: That is correct.

Mr. Elson: ——that to a very large extent, there was, but there were certain features of the two cases that were not at all identical, and for that reason I did not want to consolidate them.

So he said, "Well, let's hear them. Let's hear what you have to say."

It was left in rather a nebulous fashion.

Mr. Danielson: It was not too nebulous. Stipulations as to the records were filed on January 31 in each case, and there is listed what should be considered as a part of the record in the case. The cases themselves were not consolidated, but certain items form a part of the record in each case.

The Court: The point at issue is the same in both cases, isn't it?

Mr. Elson: The point at issue, your Honor—you know how you forget these things when you get away for a few days—the point at issue is whether or not the labeling which is involved in both cases—I think it is the same, isn't it?

Mr. Danielson: That's right, the basic point is the same.

Mr. Elson: Whether the labeling is proper.

Mr. Danielson: The law is the same in each case. The facts are slightly different.

Mr. Elson: The facts do vary.

The Court: The only question in these two cases is the question of the labeling?

Mr. Danielson: That is correct.

Mr. Elson: That is right.

The Court: And whether the labeling meets the requirements of the statute or whether it doesn't. I was just wondering if it is going to be necessary to write findings of fact and conclusions of law in both cases. What prompts me is that before, you remember, when I made a ruling denying your preliminary injunction, you came in with a list of findings of fact and conclusions of law.

Mr. Elson: Yes, I did.

The Court: But you came in only on the El-O-Pathic case. I will take it back. You did file, also, on the Hudson case.

Mr. Elson: I was sure I did, because it was a time-consuming thing to do so.

The Court: Well, all right. Then I assume, inasmuch as you have worked so hard on these findings of fact and conclusions of law once before, that it will not be such a problem for the attorneys to prepare the findings, whatever they may.

You know, this case has been with me pretty near ever since I have been on the bench. I think it is one of the first cases that was turned over to me. I have had it on my desk most of the time during the past five months.

I thought I had got rid of it. I was congratulating myself that this was going to be decided by another court and I wouldn't have to decide it, and then through a turn of the wheel, it was sent back

to me and I have been called upon to make a decision.

In a case such as this, it is pretty hard to come to some conclusion, because, usually, there are two sides to the question, and usually there is a difference of opinion. I don't think there is any unanimity of opinion as to the effect of taking these so-called drugs. I think there is medical opinion on both sides. It causes ill effects or it doesn't cause ill effects.

However, it seems to me that it is not a question of what the effect of the taking of the drugs is, but the main issue is what is on the packages, how it is described, what is said.

As counsel has pointed out, after the criminal hearing he attempted to sit down and comply with the ruling in that case. Well, the plaintiff in this case is in the position of lawyers many times when some defendant gets into trouble and comes into the office, and you say, "You shouldn't have done that." It is very easy to tell people what they shouldn't have done. It is a great deal more difficult to tell people what they should do.

I am quite sure that it has been the experience of most attorneys that when people come into your office, you say, "Well, you shouldn't have done that." After the thing is done and it doesn't turn out in the proper way, you always are in a position to say, "That was the wrong thing to do. It didn't have the proper results."

Since this matter has been submitted to me the second time, I have gone over the pleadings and I

have read your complaint and I have read your answer. I have read the argument made before Judge Cavanah, that is, according to the transcript. I have read your affidavits, too. I have come to a conclusion.

I notice—I believe it is one of the arguments of the defendants in this case—that the plaintiff says, "You can't do it this way." They never tell them how they can do it.

According to the affidavits of Mr. Elson, when he talked to someone whom he has identified as a doctor of medicine employed by the Food and Drug Administration in Washington, he asked the question whether or not any kind of a description would have been sufficient and he, purportedly, got the reply that it was the purpose to see that these products were only sold on prescription. So I am rather doubtful whether or not the defendant in this case could write any sort of matter upon a small box, upon a small container, which would meet all of the objections of the Food and Drug Administration.

It is claimed, on more than one occasion during the proceedings, that sufficient warnings were not given. Yet I have gone through the pleadings for the last time this morning, and I notice in both cases that physicians are mentioned four times.

In your original complaint, you set out the descriptive matters upon the cartons. There is no dispute as to what was printed on the cartons. The cartons are before the court. They can be read.

In all cases, on both of these cases, as far as I am

able to ascertain, the word "physician" is used at least four times, "under supervision of a physician," "under direct supervision of a physician," and I don't know what more words would be put upon their cartons that would be a greater warning, except, "to be used only upon a prescription from a physician."

I think that is what the Food and Drug people are trying to get at. That is, they want these medicines to be sold only upon the prescription of a physician.

There has been considerable testimony here about the effects that would follow if the substances are taken by persons under certain physical conditions. Again, that is a disputed fact. The doctors don't agree.

I have not been able to make up my mind that the plaintiff is entitled to the relief he has asked for in these complaints. I think the burden of proof is upon the plaintiff. At least, as far as I am concerned, the plaintiff has not sustained the burden of proof.

Consequently, I think a judgment will be entered in favor of the defendants and against the plaintiff.

Certificate

I hereby certify that I am a duly appointed, qualified and acting official court reporter of the United States District Court for the Southern District of California.

I further certify that the foregoing is a true and correct transcript of the proceedings had in the

above-entitled cause on the date or dates specified therein, and that said transcript is a true and correct transcription of my stenographic notes.

Dated at Los Angeles, California, this 27th day of March, A.D. 1950.

/s/ S. J. TRAINOR,
Official Reporter.

[Endorsed]: Filed August 2, 1950.

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[Title of District Court and Cause, No. 20,596-Criminal.]

## STIPULATION OF FACTS

The parties, through their respective counsel, agree that the only significant issue to be decided is whether the drugs involved were misbranded or were not misbranded; and so as to conserve time and to avoid testimony with respect to undisputed facts, and in order that the real issue may be promptly placed before the Court, they do agree specifically as follows:

1. Defendant Martin A. Clemens is the manager and director of defendant El-O-Pathic Pharmacy, Inc., a corporation, and also trades and does business under the firm name of M. A. Clemens Pharmacy, both businesses being located at Los Angeles, California; at all times referred to in the criminal information filed in this case, said defendant Clemens was the manager and director of said El-O-

Pathic Pharmacy, Inc., and also traded and did business under the firm name of said M. A. Clemens Pharmacy.

2. With respect to the alleged interstate and intrastate shipments and sales by the defendants of the drugs with their accompanying labeling as described in the fourteen counts of the criminal information, it is agreed that said defendants caused such shipments and sales on the dates and in the manner specified in each count.

3. With respect to the alleged interstate and intrastate shipments and sales by persons other than the defendants of the drugs described in Counts 4 through 9, inclusive, it is agreed that such shipments and sales transpired on the dates and in the manner specified in those counts.

4. The composition of each drug is as declared on the labeling of said drug, which labeling is hereinafter identified in this Stipulation and appended as exhibits; the composition of the drug involved in Count 10 (which is not declared in the labeling) is 0.5 mg. alpha-estradiol per tablet. The drug involved in Count 10 was shipped in package form.

5. Said defendants did not require or receive a physician's prescription in the shipment or sale of any of the drugs involved in Counts 1 through 14, inclusive.

6. Appended to this original Stipulation and incorporated herein are Government Exhibits 1, 1(a) etcetera through 14(a), inclusive. Said ex-

hibits have been so numbered subject to the Court's approval. Each exhibit has been given a number to be readily identified with the count to which it is relevant. In instances where there are more than one item, the second, has been marked Exhibit 1(a), 6(b), etcetera.

Government's Exhibit 1 bears the labeling referred to in Count 1; Government's Exhibit 2 bears the labeling referred to in Count 2, and to like effect with respect to Government Exhibits 3 through 14(a), inclusive, as specifically identified in each of the attached exhibits. Each item comprising this labeling is as identified in each exhibit. Each such item appears exactly as it was when received by the consignee designated in each exhibit, with the sole exception that the Food and Drug inspectors who collected these items wrote official sample numbers, dates of collection, and their initials upon each item.

The original exhibits referred to in each of the counts are attached to the original of this stipulation. The copies of this stipulation contain photostats thereof, however, so far as a certain circular or pamphlet is concerned, the copies reflect but a portion of said circular. The parties are familiar with said circular and are content to so identify it in the copies of this Stipulation without requiring it to be fully photostated. This circular is a four page printed pamphlet bearing on the front thereof, among other writings, "Male and Female Sex Hormones."

7. Each of the drugs involved in Counts 1 through 14, inclusive, was manufactured by an out-of-state manufacturer; during the interstate and intrastate journeys of said drugs from the manufacturers to the defendants, the labeling of each such drug bore the legend: "Caution: To be dispensed only by or on the prescription of a physician." In the transactions described in Counts 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, and 13, defendants repackaged the drugs as received from the manufacturers before making the shipments and sales involved in those counts. In the transactions described in Counts 3, 12, and 14, defendants shipped and sold the drugs in the original packages as received from the manufacturers. In no instance did the defendants alter the composition of any of said drugs. The circular "Male and Female Sex Hormones" did not accompany any of said drugs in their interstate or intrastate movement from the manufacturers to the defendants.

Dated: June 15th, 1949.

JAMES M. CARTER,
United States Attorney.

NORMAN W. NEUKOM,
Assistant U. S. Attorney,
Chief, Criminal Division.

/s/ GEORGE E. DANIELSON,
Assistant United States Attorney, Attorneys for United States of America.

/s/ CARL B. STRUZENACKER,
Attorney for Defendant.

Count One

GOVERNMENT'S EXHIBIT 1
(20596)

Label on a product, as received by John R. Winch, of Phoenix, Arizona.

Male Hormone

Each tablet contains 25 mg. testosterone the form of the true male sex hormones which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

| | |
|---|---|
| Trial Size | $ 2.00 |
| Box 30 Tablets | 10.00 |
| Box 60 Tablets | 19.00 |
| Box 100 Tablets Professional Size | 29.95 |

Send Mail Order to M. A. Clemens (Pharmacist)
426 So. Spring St., Room 502-503
Los Angeles 13, Calif.
MAdison 6-4171

[In Longhand]: 30-046 K 11-1-47.
JRW.

Admitted June 22, 1949.

GOVERNMENT'S EXHIBIT 1(a)
(20596)

Circular that accompanied drug, as received by John R. Winch of Phoenix, Arizona.

[In Longhand]: 30-046 K 11-1-47.
JRW.

Male and Female Sex Hormones
M. A. Clemens
(Pharmacist)

Distributors of Vitamins and Hormones
Sanitary Rubber Goods

Endocrine preparations of unusual quality for Male and Female

426 South Spring Street Rooms 502-503
Los Angeles 13, Calif.
MA. 64171 MA. 64172

Male Hormone

Testosterone

This discovery of the Male Sex Hormone is one of the achievements of modern medicine on which the public is comparatively uninformed. Yet it is truly a tremendous accomplishment.

Prof. Ruzicker, a Swiss chemist, succeeded in making Testosterone, "the most potent male hormone" by synthetic means; and for this he received The 1939 Nobel Prize in Chemistry.

"Science is unlocking the secrets of Male and Female sex hormones. Years of scientific effort and research have established that these hormones accomplish many things which up to a few years ago

were thought to be impossible. These discoveries are far-reaching and assisting millions of men and women to lead happier lives, and are relieving and postponing the many conditions associated with middle age."

The Sex Hormones

All hormones play a major part in the sexual makeup of the hormonal system. The male hormone stimulates growth and development of the sex organs and of the male sex characteristics, such as distribution of hair, muscular development, depth of voice and the improvement of a sense of well-being.

Male Hormone Deficiency

The average man in his late forties begins to enter what is called the "climacteric" period at which time the body undergoes a radical change. Although most of these changes may start during middle age, they may also show up at almost any time during middle age. As a rule there may be flushes, sweats and chills. Lack of sexual power, impaired memory, irritability, inability to concentrate on activities or a tendency to evade them, nervousness, depression, general weakness and poor physical strength are some of the major signs which are associated with this declining period.

Impotence

Lack of sexual desire and inability to perform the sexual act is one of the most common complaints of the male "climacteric." When due to a deficiency of the male sex hormone, these conditions

usually respond promptly to male hormone therapy, which assist in restoring sexual desire and ability to fulfill it. In addition to re-establishing potency, the male sex hormone helps to relieve other conditions which frequently occur during this period.

Results From Male Hormone

These social, sexual, physical and mental conditions may be overcome by the use of the male sex hormones, which often bring about startling changes. At first, it may be noticed there is a marked improvement in physical and mental work and a tonic action resulting in renewed vigor. A better attitude towards business and social life is frequently observed. Nervousness, exhaustion and melancholy gradually disappear and in the large majority of instances the improvement persists over a long period of time.

Just One Tablet a Day and Eliminate
Unnecessary Injections
New 25 mg Tablet

| | |
|---|---|
| 30 Tablets | $10.00 |
| 100 Tablets | 29.95 |
| 200 Tablets | 57.50 |

No Prescription Required
Add 3% Sales Tax for Mail Orders

Prices on Testosterone for Injection by Request

Male Hormone

Linguets . . . under the tongue

when Oroal Male Hormone Therapy is Indicated

are effective in doses ½ to ⅔ the amount required when methyl testosterone is ingested. Greater economy, convenience and ease of administration mark Metandren Linguets as one of the great advances in androgenic therapy.

The Most Economical Oral Androgen

The sublingual administration of methyl testosterone in the form of Linguets is based on direct venous drainage from the oral mucous membranes. The androgen is carried in the blood by the systemic venous system to the right heart, thence through the pulmonary circulation back to the left heart and thus is first distributed by the general circulation to all organs and tissues. By this route methyl testosterone by-passes the liver and escapes partial inactivation. Consequently, complete dosage is delivered to the tissues more rapidly and without loss.

Regular Strength

Box 50 Tablets Linguets..$ 7.00 plus 3% sales tax
Box 100 Tablets Linguets.. 13.00 plus 3% sales tax
Box 200 Tablets Linguets.. 25.00 plus 3% sales tax
Box 500 Tablets Linguets.. 60.00 plus 3% sales tax

Double Strength

Box 100 Tablets Linguets..$17.00 plus 3% sales tax

No Prescription Required

Many excellent Reports for the Non Professional layman have already appeared in the following publications:

Readers Digest by Paul de Kruif, July, 1944 —August, 1946.
Newsweek, March, 1943.
Time, May 28, 1945.
Newsweek, May 28, 1945.
Liberty, February 2, 1946.
*Paul de Kruif's sensational book, "The Male Hormone," Harcourt-Brace.

Information and Prices on Ampules or Vials Sent by Request

Female Hormone
A-Estradial

The estrogenic hormone promotes the development of sex characteristics in the female.

It maintains the normal condition of these characteristics in the normal adult woman.

a-Estradiol preparations confer a definite "sense of well-being."

a-Estradiol offers clinically important advantages.

a-Estradiol is the genuine hormone of the ovarian follicle, which is "probably the most potent of all known estrogens."

a-Estradiol has a smooth, dependable action which speedily controls the symptoms of ovarian

---

*Send $1.00 plus 15c for mailing.

deficiency and produces a gratifying sense of well-being. a-Estradiol is not likely to provoke side reactions or after-effects, such as headache, dizziness and gastrointestinal disturbances, which frequently complicate the action of artificial estrogens. Because of their high potency, oral a-estradiol tablets may be used in place of parenteral therapy in most cases. The elimination of frequent injections means not only more comfort and convenience for the patient—it also saves the physician both time and energy.

The especial therapeutic value of a-estradiol preparations, particularly as compared with estrone (theelin) and estriol (theelol), is today widely appreciated, since the latter now appear to be secondary products of minor importance.

The Change of Life

Although this period which occurs between the fourth and fifth decades of life may pass with hardly any complaints, in many women it may cause disorders which may interfere seriously with normal living. These disorders may be mild or severe, depending upon the individual. Headache, insomnia and dizziness are frequently complained of. In severe cases, there may be fear, crying spells sometimes accompanied by melancholy and emotional instability.

Prices—A-Estradiol Tablets

30 Days Supply ..... $10.00
60 Days Supply ..... 17.50

Breast Development

Direct Action on the Mammary Gland

Estrogens can be absorbed through the skin of the human female directly into the breast tissue and by this route can produce their characteristic stimulation of mammary growth and the result is "definite breast growth of considerable degree." Since underdeveloped breasts are often a considerable worry to women, cutaneous estrogen therapy of hypomastia presents a valuable addition to the physician's therapeutic resources.

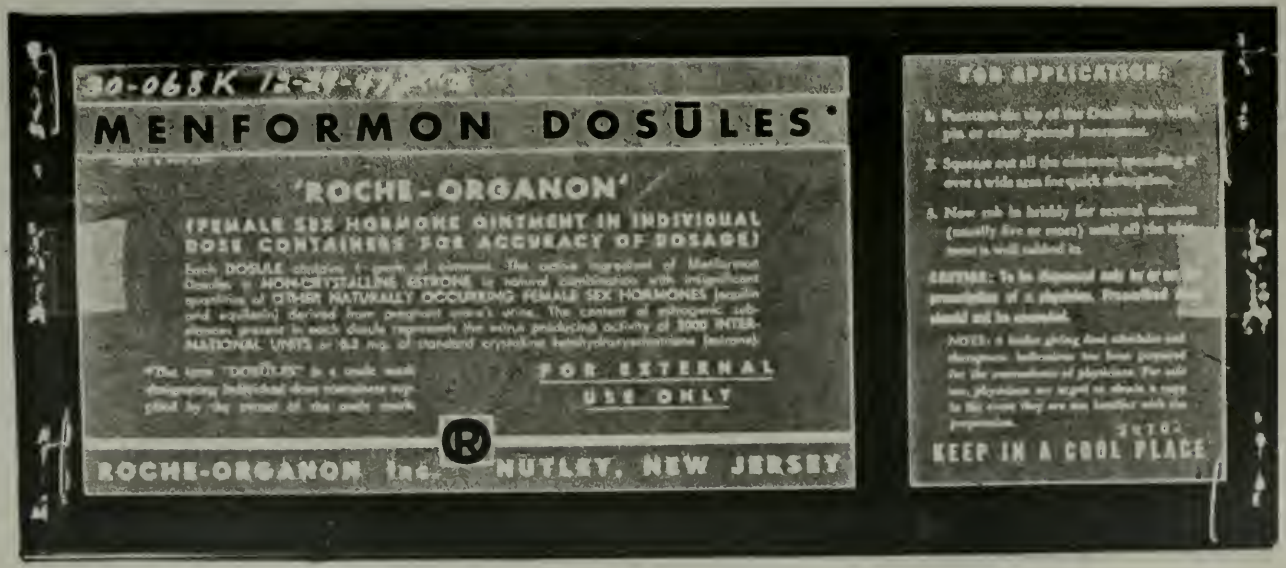
25 Days Supply (50,000 International Units) ..... $ 7.50

25 Days Supply (125,000 International Units) ..... 14.00

No Prescription Required

Government's Exhibit 3(a). Photostat of above label taken before label was slightly torn in being removed from box.

GOVERNMENT'S EXHIBIT 3(a) (20596)



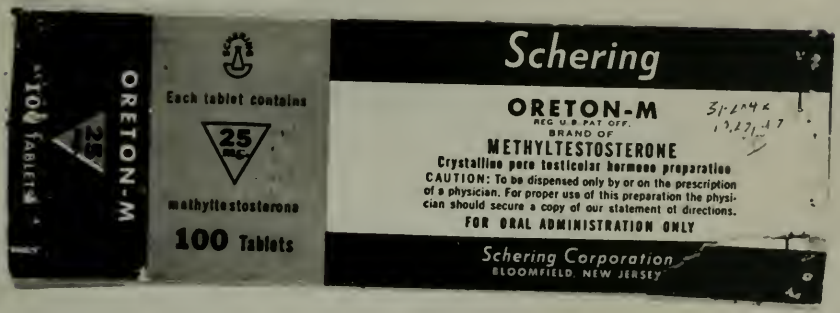

Admitted June 22, 1949.

Count Six

Government's Exhibit 6. Label on carton of drug, as received by Forum Drug Co., and by M. A. Clemens Pharmacy, both at Los Angeles, California.

Front View

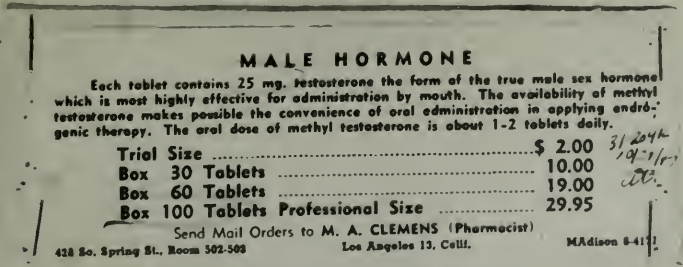
GOVERNMENT'S EXHIBIT No. 6 (20596)




Admitted June 22, 1949.

Government's Exhibit 6(a). Label on envelope of drug, as received by Alan T. Spiher.

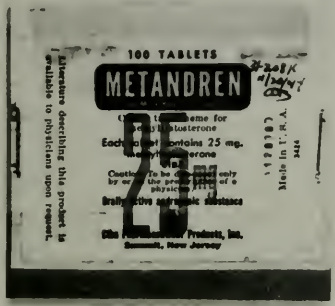
GOVERNMENT'S EXHIBIT 6(a) (20596)




Admitted June 22, 1949.

COUNT EIGHT

Government's Exhibit 8. Label on bottle of drug, as received by El-O-Pathic Pharmacy at Los Angeles, California.




Government's Exhibit 8(a). Label on envelope of drug, as received by Alan T. Spiher.

31-208K
11/20/47
ATS
Exhibit C

NOTE: Please understand this ... size is simply an introductory package an... r market results treatment must be continued over a 30-day period.

MALE HORMONE

Each tablet contains 25 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying endrogenic therapy. The oral dose of methyl testosterone is about 1-2 tablets daily.

| | | |
|---|---|---|
| (Trial) | Size | $ 2.00 |
| Box | 30 Tablets | 10.00 |
| Box | 60 Tablets | 19.00 |
| Box | 100 Tablets Professional Size | 29.95 |

31-208K 11/20/47 ATS Exhibit C

Send Mail Orders to EL-O-PATHIC PHARMACY

1109½ No. Western Ave. Hollywood 27, Calif. HOllywood 1721

Count Thirteen

Government's Exhibit 13, label on bottle of drug, as received by D. J. McBride, at Tucson, Arizona.

GOVERNMENT'S EXHIBIT No. 13
(20596)

Male Hormone

Each tablet contains 5 mg. testosterone the form of the true male sex hormone which is most highly effective for administration by mouth. The availability of methyl testosterone makes possible the convenience of oral administration in applying androgenic therapy.

The oral dose of methyl testosterone is 2 tablets 3 times daily. Place 2 tablets under the tongue and allow them to dissolve.

Box 50 Tablets Linquets .....$ 7.00
Box 100 Tablets Linquets ..... 13.00

Send Mail Orders to
M. A. CLEMENS (Pharmacist)
426 So. Spring St., Room 502-503,
Los Angeles, 13, Calif.
Successor to Clark's Drugs & Sundries

Admitted June 22, 1949.

[Longhand]: 31-220 K 1/30/48.
AB.

[Endorsed]: Filed June 22, 1949.

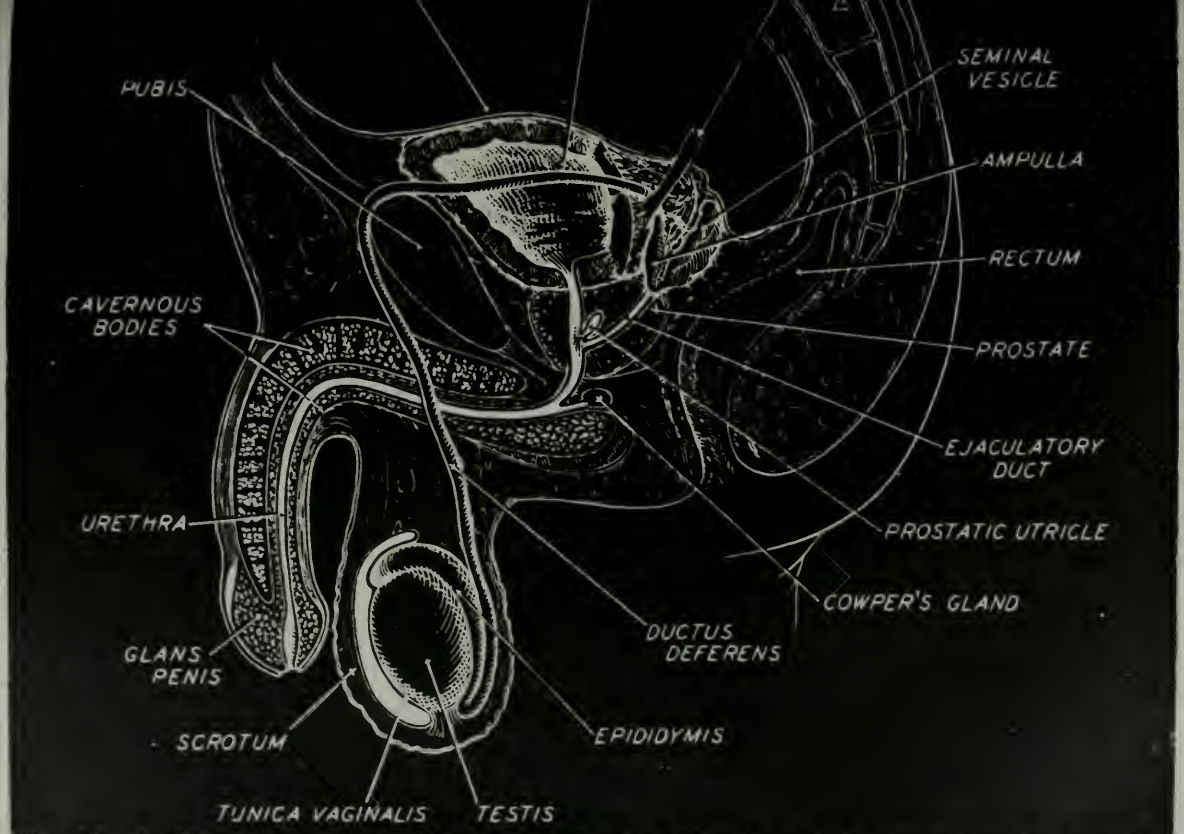



Fig. 51. A diagrammatic sagittal section of the male pelvis, showing the genital organs and their relations to the bladder and urethra.

GOVERNMENT'S EXHIBIT No. 18
(20596)

Hormone Preparations
Memo to Chief
3/25/48
AB.
Roche-Organon Inc.
Nutley 10, New Jersey

Hormones

July 1947

Gentlemen:

One of our most popular dealer helps is our literature imprinting service. Demands for Roche-Organon literature bearing the name and address of the individual dealer have increased by leaps and bounds. Because of the growing popularity of this service and because a number of dealers have only recently become Roche-Organon distributors, we should like to repeat and reemphasize the salient points of this service.

As you know, it is the firm policy of Roche-Organon never to advertise its products to the laity; therefore, the literature which you request and receive is for distribution only to your physicians. In fact, all of the more recent Roche-Organon literature bears this legend: "This pamphlet has been prepared for dissemination to the medical profession exclusively."

All Roche-Organon products, with the exception of Cytora, are strictly prescription items; literature, therefore, must be kept out of the hands of your

customers. You would be breaking faith with your physicians to do otherwise. In fact, you might even endanger lives, for hormones are powerful therapeutic agents which must be administered under strict medical supervision.

So pass along these facts to all your clerks: (1) Roche-Organon literature is for physicians only. (2) Keep Roche-Organon literature out of reach of your customers. (3) All Roche-Organon products (except Cytora) bear an Rx legend on their labels, and therefore may be dispensed only on a physician's prescription. (4) Don't give out literature with prescriptions for Roche-Organon products even when the patient asks for it.

Strict observance of these rules means that the professional standing of your store will rise. Your physicians will regard your store as a truly professional hormone headquarters.

Sincerely yours,

/s/ ROCHE-ORGANON, INC.

NAL:GF

Admitted July 5, 1949.

(Advertisement taken from the Los Angeles Times--Page 32 Part 1, April 17, 1949.)


**Get this Great 246-page Book originally published at $2.50 with 50 methyl testosterone LINGUETS**

**Both for $5.15** *including tax*

# OVER 40? *Nervous? Depressed?*

Easily tired? Forgetful—confused—think you ore no longer "good for much"? If you have felt any or all of these discouraging symptoms, you should read this splendid, hope-inspiring volume. Then try magic methyl testosterone, that Dr. Albert Hemming, noted authority, states "can go far toward revitalizing o man who is going through a male 'change of life.'"

This is *your opportunity* to prove it for yourself. Here is o large enough quantity for a reol test, ot the lowest cost yet offered—and in o form TWICE AS EFFECTIVE as tablets you swallow—LINGUETS that *melt* under your tongue and are absorbed *directly* into the system.

Don't put off the new life, energy, hoppiness that may be yours! Send cash, check, money order (or order C.O.D.) with the coupon TODAY! Or come in and see our REGISTERED PHARMACIST.

Other *guaranteed* hormone products for women—

**FEMALE HORMONES** MONTH'S SUPPLY—SPECIAL **$5.15** incl. tax

**BREAST DEVELOPMENT** 25 APPLICATIONS OF HORMONES **$7.73** incl. tax

**FREE LITERATURE!** **FREE PARKING!** **PHONE HO 9-1722**

**ELOPATHIC PHARMACY, Dept. T-4,**
**1109½ No. Western Ave., Hollywood 27, Calif.**

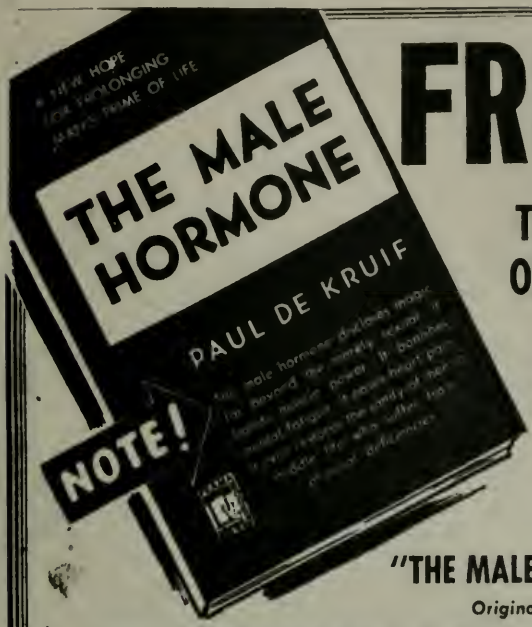
☐ ENCLOSED FIND $5.15 FOR 50 LINGUETS AND THE MALE HORMONE BOOK
☐ $5.15 FOR FEMALE HORMONE (tax incl.) ☐ $7.73 for BREAST DEVELOPMENT

NAME .....

ADDRESS CITY & STATE

Admitted July 6, 1949.

(Advertisement taken from the Los Angeles Times--Date 22, Part 1, June 8, 1949.)




# FREE!

## TO MEN OVER 40

SPECIAL OFFER
LIMITED TIME!

Paul De Kruif's great book

**"THE MALE HORMONE"**

*Originally $2.50*

**WITH PURCHASE OF 50 LINGUETS**

Regularly $7.50 — BOTH NOW ONLY — **$5.00** Plus 15c Sales Tax

---

**NERVOUS? TIRED? DEPRESSED?**

Now Try Double Effective

# MALE HORMONES

Don't put off new life—renewed energy and happiness that may be yours! A 30 to 50-day trial will prove how much more vigorous—alert—alive you may feel! How much more vital in your home and business life! Try magic methyl testosterone, that Dr. Albert Hemming, noted authority, states "can go far toward revitalizing a man who is going through a male 'change of life'." Methyl testosterone linguets melt under the tongue . . . get into the system directly . . . DOUBLE the effect of tablets you swallow!

**FEMALE HORMONES** — MONTH'S SUPPLY, SPECIAL — $5.00 add 15c tax
**Breast Development** — 25 APPLICATIONS OF HORMONES — $7.50 add 23c tax
FREE LITERATURE — FREE PARKING — PHONE NO. 9-1722
REGISTERED PHARMACISTS

ELOPATHIC PHARMACY, Dept. 2-4,
1109½ No. Watsern Ave., Hollywood 27, Calif.
☐ ENCLOSED FIND $5.15 FOR 50 LINGUETS AND "THE MALE HORMONE" BOOK.
☐ $5.15 FOR FEMALE HORMONE (tax incl.) ☐ $7.73 for BREAST DEVELOPMENT.

NAME _____

ADDRESS _____ CITY & STATE _____

Admitted July 6, 1949.

GOVERNMENT'S EXHIBIT No. 24
(20596)

(Advertisement taken from the Los Angeles Daily News, Page 8-B, July 5, 1949.)

Over 40?
Now—Try

Doubly Effective
Male Hormones

Find out how much more vigorous, alert, alive you may feel—how much more vital in your home and business life!
For a real test, you need 30 to 50 days. So for a short time, we make this unprecedented

Special Offer!
50 Linguets, $5.00
add 15c sales tax

Lowest price ever for the most effective way to take methyl testosterone, the genuine Male Hormone! They melt under the tongue—get into the system directly—Double the effect of tablets you swallow! Send cash, check, money order (or order C.O.D.) Now! Other guaranteed hormone products also mailed first class, in plain wrapper.

Female Hormones
Month's Supply—Special—$5.00
add 15c sales tax
Breast Development
25 applications, $7.50
add 23c sales tax

Don't delay—send in
your order Now!

Elopathic Pharmacy
Dept. T-5
1109½ N. Western Ave.
near Santa Monica Blvd.
Los Angeles 27, Calif.
Registered pharmacist in attendance
Free Parking! Free Literature!

Admitted July 6, 1949.

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DEFENDANT'S EXHIBIT B
(20596)

Report of Dangerous Drug Committee, State Board of Pharmacy, March 24, 1948

Report based on information obtained through four public hearings and 16 responses to questionnaire from experts.

1. Two hearings held on Estrogenic substances, one in Los Angeles and one in San Francisco.

2. Two hearings held on Estrogenic and Androgenic Sterols, one in Los Angeles and one in San Francisco.

3. 16 questionnaires returned from Medical experts.

Of the 16 questionnaires returned on the question of the Carcinogenic properties of Estrogenic substances there were eleven Noes and 5 Yeses.

On the question of Dangerous Properties and question of restriction, there were 16 Yeses to both

questions but very little supporting evidence to show why they were dangerous.

The public hearings were not well attended, which signifies that there is little public interest in the matter. Most of those present were of the opinion that Estrogenic Substances should be restricted, but no evidence was brought out as to why this should be done and no specific case of injury to anyone was cited. There were some vague references to "bleeding" being produced in some patients.

On the question of Androgenic Substances, no evidence was presented to indicate that they were harmful and no specific case of injury was cited. The preponderance of evidence seemed to be that they are not harmful or dangerous, except that they might "light up" an incipient cancer of the prostate.

Conclusion of the Committee

In the absence of any specific cases of harmful effect attributable to the substances considered and due to lack of interest and any demand on the part of the public, the committee feels that no action should be taken by the Board at this time. But that we should await the results of the study now being undertaken by the Federal Government.

The committee further recommends that it be kept standing and continue its study of the problem. And that it endeavor to obtain information relative to the volume and extent of use of estrogenic substances for self medication.

/s/ A. J. AFFLECK,
Chairman.

Admitted July 6, 1949.

[Title of District Court and Cause. No. 20642—Criminal.]

## STIPULATION OF FACTS

The parties, through their respective counsel, agree that the only significant issue to be decided is whether the drugs involved were misbranded or were not misbranded; and so as to conserve time and to avoid testimony with respect to undisputed facts, and in order that the real issue may be promptly placed before the Court, they do agree specifically as follows:

(1) Defendant Allen H. Parkinson is an individual trading and doing business under the firm name of Hudson Products Company at Long Beach, California: at all times referred to in the criminal information filed in this case, said defendant Parkinson was trading and doing business under said firm name of Hudson Products Company at Long Beach, California.

(2) With respect to the defendant's alleged interstate shipments and sales of the drugs with their accompanying labeling as described in the four counts of the criminal information, it is agreed that said defendant caused such shipments and sales on the dates and in the manner specified in each count.

(3) The composition of each drug is as declared on the labeling of said drug, which labeling is hereinafter identified in this Stipulation and appended as exhibits.

(4) Said defendant did not require or receive a physician's prescription in the shipment or sale of any of the drugs involved in Counts 1-4, inclusive.

(5) Appended to this original Stipulation and incorporated herein are Government's Exhibits 1, 1(a), et cetera, through 4(b), inclusive. Said exhibits have been so numbered subject to the Court's approval. Each exhibit has been given a number to be readily identified with the count to which it is relevant. In instances where there are more than one item, the succeeding items have been marked Exhibit 1(a), 4(b), et cetera.

Government's Exhibit 1 bears the labeling referred to in Count 1; Government's Exhibit 2 bears the labeling referred to in Count 2, and to like effect with respect to Government's Exhibits 3 and 4, as specifically identified in each of the attached exhibits. Each item comprising this labeling is as identified in each exhibit. Each such item appears exactly as it was when received by the consignee designated in each exhibit, with the sole exception that the Food and Drug inspectors who collected these items wrote official sample numbers, dates of collection, and their initials upon each item.

The original exhibits (in some instances, photostats thereof) referred to in each of the counts are attached to the original of this stipulation. The copies of this stipulation contain photostats thereof; with respect to the leaflets comprising some of the exhibits, the copies reflect but a portion of such leaflets. The parties are familiar with said leaflets

and are content to identify them in this manner in the copies of this stipulation without requiring them to be fully photostated. These leaflets are respectively entitled "The Male Hormone" and "The Story of Hormones."

(6) Each of the drugs involved in this case was manufactured by an out-of-state manufacturer; during the interstate and intrastate journeys of said drugs from the manufacturers to the defendant, the labeling of each such drug bore the legend: "Caution: To be dispensed only by or on prescription of a physician." Defendant repackaged the drugs as received from the manufacturers before making the shipments and sales involved in this case. In no instance did the defendant alter the composition of any of said drugs. Neither the leaflet entitled "The Male Hormone," nor the leaflet entitled "The Story of Hormones" accompanied any of said drugs in their interstate or intrastate movement from the manufacturers to the defendant.

(7) It is expressly agreed that the Court may consider the evidence produced in this Court in the case of United States v. El-O-Pathic Pharmacy, Inc., et al., No. 20,596—Criminal, to be a part of the record in the instant case, insofar as such evidence is pertinent here, the same as if such evidence had been given in the trial of the instant case, subject to the same objections as were originally raised in the presentation of such evidence. It is further expressly agreed that both parties reserve the right to

offer any additional evidence that is relevant, competent, and material.

Dated: July 7th, 1949.

JAMES M. CARTER,
United States Attorney.

NORMAN W. NEUKOM,
Assistant United States Attorney, Chief, Criminal Division.

/s/ GEORGE E. DANIELSON,
Assistant United States Attorney, Attorneys for United States of America.

/s/ EUGENE M. ELSON,
Attorney for Defendant.

Count One

Government's Exhibit 1. Label on carton of drug as received by Roy H. Downing of Altoona, Pennsylvania.

GOVERNMENT'S EXHIBIT No. 1
(20642)

Male Sex Hormones
(30) 10 Mg. Methyl-Testosterone Tablets

Dosage: 1 Tablet Daily

Important—In case of pronounced male sex hormone deficiency take 3 tablets daily for 10 days.

After the 10 day period take 1 tablet daily.

Caution: Take Only as Directed.

Hudson Products Co.
341 Harding Street, Long Beach 5, Calif.

[Stamped]: 6-134 K Jul. 16, 1948.

[Initialed]: D.F.F.

Government's Exhibit 1(a). Leaflet "The Male Hormone" that accompanied drug, as received by Roy H. Downing of Altoona, Pennsylvania.

GOVERNMENT'S EXHIBIT No. 1(a)
(20642)

The Male Hormone
Methyl-Testosterone
The True Male Sex Hormone

★

This discovery of the Male Sex Hormone is one of the achievements of modern medicine on which the public is comparatively uninformed. Yet it is truly a tremendous accomplishment.

Prof. Ruzicker, a Swiss chemist, succeeded in making Testosterone, "the most potent male hormone" by synthetic means; and for this he received The 1939 Nobel Prize in Chemistry.

"Science is unlocking the secrets of Male and Female sex hormones. Years of scientific effort and research have established that these hormones accomplish many things which up to a few years ago were thought to be impossible. These discoveries are

far-reaching and assisting millions of men and women to lead happier lives, and are relieving and postponing the many conditions associated with middle age."

### The Sex Hormones

All hormones play a major part in the sexual makeup of the hormonal system. The male hormone stimulates growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development, depth of voice and the improvement of a sense of well-being.

### Male Hormone Deficiency

The average man in his late forties begins to enter what is called the "climacteric" period at which time the body undergoes a radical change. Although most of these changes may start during middle age, they may also show up at almost any time during middle age. As a rule there may be flushes, sweats and chills. Lack of sexual power, impaired memory, irritability, inability to concentrate on activities or a tendency to evade them, nervousness, depression, general weakness and poor physical strength are some of the major signs which are associated with this declining period.

### Impotence

Lack of sexual desire and inability to perform the sexual act is one of the most common complaints of the male "climacteric." When due to deficiency of the male sex hormone, these conditions usually respond promptly to male hormone therapy, which as-

sist in restoring sexual desire and ability to fulfill it. In addition to re-establishing potency, the male sex hormone helps to relieve other conditions which frequently occur during this period. [385]

Results From Male Hormone

These social, sexual, physical and mental conditions may be overcome by the use of the male sex hormones, which often bring about startling changes. At first, it may be noticed there is a marked improvement in physical and mental work and a tonic action resulting in renewed vigor. A better attitude towards business and social life is frequently observed. Nervousness, exhaustion and melancholy gradually disappear and in the large majority of instances the improvement persists over a long period of time.

Many excellent Reports for the Non Professional layman have already appeared in the following publications:

Readers Digest by Paul de Kruif, July, 1944—August, 1946.
Newsweek, March, 1943.
Time, May 28, 1945.
Newsweek, May 28, 1945.
Liberty, February 2, 1946.
Paul de Kruif's sensational book, "The Male Hormone."

★

Just One Tablet a Day

15 Day Supply ..... $ 6.00
30 Day Supply ..... 10.00
90 Day Supply ..... 24.00

Mailed in Plain Package

Send Check or Money Order

C.O.D.'s Accepted—Plus Postage

All Orders Sent Airmail

Same Day Received [386]

★

The Female Hormone

(A Estradiol)

The use of Female sex hormones usually brings prompt relief from such symptoms as hot flashes, emotional disturbances and other manifestations associated with the menopause. A steady readjustment may be obtained from the use of natural hormones, which help to overcome most menopausal conditions in women approaching or passing through this period.

Just One Tablet a Day

30 Day Supply ..... 5.00
90 Day Supply ..... 12.00

Mailed in Plain Package

Send Check or Money Order

C.O.D.'s Accepted—Plus Postage

All Orders Sent Airmail

Same Day Received

Relatively Safe

The Male and Female sex hormones as a rule are

relatively safe to use; however, they should be used cautiously by some individuals. The Female sex hormone should not be used by women with cancer or pre-cancerous lesions of the breast or genital organs and should be used with care by women with a family history of frequent incidence of breast or genital cancer. The Male sex hormone should be carefully used by elderly men with cardivascular disturbances and should not be used if there is any indication of cancer of the prostate.

Caution: Take only as directed.

Hudson Products Co.
341 Harding St.
Long Beach 5, Calif. [387]

[Stamped]: 6-134 K July 16, 1948.
/s/ D. F. F.

[Initialed]: R. H. D. 7/16/48

Count Three
(Continued)
(20642)

GOVERNMENT'S EXHIBIT 3(b)

Leaflet "The Story of Hormones" that accompanied drug, as received by Armond W. Welch of Seattle, Washington.

37-357/58 K
6-21-48 AMW

THE STORY OF HORMONES

Hudson Products Company, Long Beach, Calif.

Index

★

THE STORY OF HORMONES

Hudson Products Company, Long Beach, Calif.



37-357/58K

How It All Began . . .

Far-reaching discoveries about male and female sex hormones are among the important achievements of modern medicine on which the general public is comparatively uninformed. Yet recent scientific research has established beyond doubt that treatment with hormones can bring about human benefits be-

lieved impossible until a few years ago.

As a result of incessant experiments with first the male and then the female hormones, science today assists millions of men and women to lead happier lives. Many conditions formerly thought to be inevitable with middle age can now be relieved.

For years certain scientists experimented with extracts and compounds of the sex hormones without satisfying results. Then, in 1935, came the first real step toward today's tremendous accomplishments with hormones—the isolation of a crystalline potent androgen from a bull's testes by a man named Laquer and his associates in Amsterdam. Laquer called the new substance "Testosterone." Today methyl testosterone is recognized as the most potent form of the male hormone.

Following Laquer's discovery a Swiss chemist, Prof. Ruzicker, succeeded in making testosterone by synthetic means. Ruzicker's work confirmed the structure of natural testosterone and won him the 1939 Nobel Prize in Chemistry. Androgenic (male hormone) therapy was thus removed from the realm of speculation and the unbiased scientific study of the physiologic and therapeutic activity of the sex hormone began in earnest.

### How Hormones Affect Physical Development and Processes

From puberty to late middle life, and sometimes even in old age, the testes (stimulated by the anterior pituitary gland) produce appreciable amounts of the male sex hormone. Absorbed into the blood stream, which carries it to all parts of the body, the male

sex hormone has a variety of functions. For convenience they may be divided into four groups:

1. Influence on male reproductive organs
2. Influence on secondary sex characteristics
3. Influence on other endocrine glands
4. Influence on other organs, tissues and metabolic processes [400]

### How Hormones Affect Male Reproductive Organs

The primary function of the male sex hormone is to regulate development and growth of the male reproductive organs. Even before a child is born, male sex hormone production is stimulated by the anterior pituitary gland of the mother-to-be, thus exerting its effect on the fetus.

Proper growth during puberty of the penis, scrotum, prostate, seminal vesicles, and Cowper's gland depends upon the presence of the androgenic (male) hormone. It may also be responsible for early descent of the testes. The male reproductive organs cannot function properly even after full development without an adequate supply of the male sex hormone. Sexual desire and potency are entirely dependent upon the amount and activity of the hormone.

### How Hormones Affect Secondary Sex Characteristics

An increase of the androgenic hormone during puberty promotes development of secondary sex characteristics. Accordingly, in men, facial and

pubic hair appears. The masculine type of skeleton and muscles develop. Fat deposits are distributed in such a way as to form the masculine type figure. The voice deepens, and the masculine behavior pattern of aggressiveness, vigor, and self confidence also becomes evident. It is interesting to note that marked muscular development has been promoted in animals and in men by the therapeutic administration of the male sex hormone.

Concerning Male Disorders

The Male Climacteric or "Change of Life"

The climacteric in women is clearly defined because of cessation of menstruation. Since men do not menstruate, it was assumed for a long time that they did not have a climacteric. The male climacteric develops gradually, progresses slowly, and may occur relatively early or late in life. Thus it often represents a complex and confusing diagnostic problem.

During this transitional period of involutional gonadal changes, some men are subject to a variety of distressing and discouraging complaints which may seriously interfere with their capacity for work or enjoyment of leisure. Symptoms which are troublesome in one patient may be entirely absent in another, and concommitant complaints of nonhormonal origin may add to the diagnostic difficulties of a particular case.

Although manifestations of the male climacteric are most frequent in patients in their forties and fifties, (the average age in women is 40.8) the pos-

sibility of hormonal imbalance must not be overlooked in younger men. Cases in the fourth and seventh decades of life are by no means uncommon. For men from 50 to 65 who complain of vague and often apparently unrelated symptoms (and who under careful study reveal signs of the climacteric) use of methyl testosterone has been urged. [401]

### Symptoms of the Male Climacteric

The discomfort men suffer during the climacteric results principally from subjective rather than objective symptoms. These symptoms are classified as (1) nervous, (2) circulatory, and (3) general.

### Nervous Symptoms

Practically all patients who can be considered to be suffering from this condition have a feeling of nervous tension or "intense subjective nervousness. There is "inward tremulousness" which is aggravated by fatigue or excitement. Many are nervous and irritable to the extent that they are exceptionally hard to get along with. Ordinary small mishaps, arguments and annoyances which are normally of little importance occasion considerable nervous and mental disturbance. Many patients complain that they wake up at night and find their hands and arms, or feet and legs, numb. There may also be itching, prickling, or tingling of the skin. Headaches of the non-migrainous type often occur. The two types of headache which are most important from a diagnostic point of view are (1) those in which there is a feeling of great weight upon the

head or a feeling of pressure; and (2) those in which the pain may radiate to the neck over the back of the shoulders and down the spine. The latter type headache may last from a few hours to several days, often causing the patient to complain of a mental haziness for days.

A decrease in the ability to concentrate and faulty memory is frequently complained of, and depression or melancholia are often encountered. Intellectual changes in male climacteric patients have been described as "lack of interest in social and business life, lack of mental concentration and energy . . . a feeling of inadequacy or impotency. Occasionally the individual conceives himself to be useless, hopeless and burdensome."

Circulatory Symptoms

Hot flashes occurred in about a third of recent case studies. They are usually of short duration but are very uncomfortable and patients sometimes compare them to feelings of smothering. They may be accompanied by sweating and chilly, creepy sensations.

General Symptoms

This group of symptoms includes tiring easily, decrease in potency and libido, constipation and the tendency to gain excessive weight.

Vague digestive complaints and precordial, angina pectoris-like pains may also be outstanding symptoms. Urinary symptoms, such as frequency, nocturia, dribbling and inability to start urinary stream are invariably associated with changes in the prostate and seminal vesicles.

### Treatment for Male Climacteric

The gratifying effectiveness of replacement therapy with male hormones in the male climacteric has been confirmed by a large number of observers. Adequate hormone therapy produces in many cases "genuinely desirable results." Patients who have feared they might be mental cases because of depression and nervous instability gradually regain confidence in their mental reactions and decisions. Patients usually report that they regain their grip on life shortly after the start of treatment, and their capacity for mental and physical work is often notably increased. [402]

### Impotence

As has already been mentioned, decreased sexual desire or complete impotence may accompany the male climacteric, though it may occur also at other times. Indeed, adequate sexual competence depends upon the integrated co-operation of several factors. Anatomic, hormonal, neurologic, psychologic, and emotional components are involved in the attainment of full potency. Impotence may be caused by a disturbance of one or several of these factors.

When impotence is caused by male sex hormone deficiency, replacement therapy with methyl testosterone is indicated. In most cases this will restore sexual desire, potency and genital tract tone with adequate sexual competence. At the same time there is often an improvement in physical and mental mal-conditions. Methyl testosterone is especially

beneficial in young and middle aged men with diminished potency, who were formerly normal.

The Female Hormone

Women, too, can find extraordinary benefits in the therapeutic administration of the sex hormone. Prompt relief is obtainable from such unpleasant menopause disturbances as hot flashes, emotional upsets and other "change of life" manifestations. A steady readjustment may occur through the use of the natural hormone, which helps overcome most menopausal conditions in women approaching or passing through this period.

Hormonal Treatment for Breast Development

Small or undeveloped breasts are frequently a cause of worry to some women. In the form of a specially prepared and medically approved ointment, the female sex hormone used for therapy produces a direct action on the mammary gland. Applied directly to the breast, this hormonal ointment stimulates growth considerably, yet helps retain the pointed shape of the young breast. The desired stimulation results from a re-vitalized concentration of the sex hormone in the body tissue. Marked results are obtainable after 60 to 90 days use.

25 Day Supply of Ointment
(125,000 International Units).....$12.95

2½ Month Supply of Ointment
(375,000 International Units).....$33.95

Warning

Although both male and female sex hormones are relatively safe to use as a rule, scientific tests prove that they should not be used by anyone suffering from cancer. Neither should they be used by persons suffering from serious heart trouble. Also, hormone therapy should be used with caution by senile men in whom excessive stimulation of waning sex power may be physiologically undesirable. [403]

New Low Prices

The Male Hormone

30 day supply..... 10.00
90 day supply..... 30.00

The Female Hormone

30 day supply.....$ 5.00
90 day supply..... 15.00

Mailed in plain package Air Mail same day order received. Send cash, check or money order.

C.O.D. you pay postage

★

Hudson Products Co.
341 Harding St.
Long Beach 5, Calif. [404]

COUNT FOUR

Government's Exhibit 4. Label on carton of drug as received by Armond W. Welch of Seattle, Washington.

(20642)

Female Hormones

(30) 0.1 Mg. Cryst. a-Estradiol

Important: In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily or as directed by your physicians.

Warning: The female hormone should not be used by women with cancer or pre-cancerous lesions of the breast or genital organs.

Not for use by children. Caution—take only as directed.

Hudson Products Co.
341 Harding St., Long Beach 5, Calif.
37-358 K 8-6-48 A. M. W.

[In Longhand]: Opened 8/20/48 J.P.G.
Received 8/13/48

[Endorsed]: Filed July 7, 1949.

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[Title of District Court and Cause No. 10391-HW]

CERTIFICATE OF CLERK

I, Edmund L. Smith, Clerk of the United States District Court for the Southern District of California, do hereby certify that the foregoing pages numbered from 1 to 420, inclusive, contain the original Complaint for Injunction; Separate Affidavits

of Clinton Hobart Thienes, Elmer Belt, and Ian Macdonald; Order Granting Temporary Restraining Order; Affidavit of Robert S. Roe; Order to Show Cause; Stipulation, Consent and Order filed Sept. 7, 1949; Amendment to Complaint for Injunction; Stipulation, Consent and Order filed Oct. 3, 1949; Answer of Defendant Martin A. Clemens et al; Affidavit of Eugene M. Elson; Affidavit of Martin A. Clemens; Supplemental Affidavit of Martin A. Clemens filed Oct. 24, 1949; Supplemental Affidavit of Martin A. Clemens filed Nov. 1, 1949; Affidavit of Lewis A. Schinazi; Stipulation and Order Permitting Filing of Amendment to Answer; Amendment to the Answer; Stipulation and Order filed Jan. 17, 1950; Affidavit of Walter F. McRae; Affidavit of Albert H. Wells; Supplemental Affidavit of Robert S. Roe; Findings of Fact and Conclusions of Law on Prayer for Preliminary Injunction; Stipulation as to Record; Findings of Fact and Conclusions of Law; and Judgment in the case numbered 10266-HW-Civil; Complaint for Injunction; Order to Show Cause; Affidavit of Robert S. Roe; Stipulation Regarding Medical Affidavits; Stipulation and Order for Continuance filed Oct. 21, 1949; Answer of Hudson Products Company et al; Affidavit of Allen H. Parkinson; Stipulation and Order Permitting Filing of Amendment to Answer; Amendment to the Answer; Stipulation and Order filed Nov. 10, 1949; Findings of Fact and Conclusions of Law on Prayer for Preliminary Injunction; Stipulation as to Record filed Jan. 31, 1950; Stipulation as to Record filed April 14, 1950; Findings

of Fact and Conclusions of Law; and Judgment in the case numbered 10391-HW-Civil; Information and Stipulation of Facts in case No. 20596-Criminal entitled United States of America, plaintiff, vs. El-O-Pathic Pharmacy, Inc., et al, Defendants; Information and Stipulation of Facts in case No. 20642-Criminal entitled United States of America, plaintiff, vs. Allen H. Parkinson etc., Defendant; Notice of Appeal; Statement of Points on Appeal and Designation of Record in Appeal in cases Nos. 10266-HW and 10391-HW; and full, true and correct copies of minute orders entered January 31, 1950 and February 3, 1950 in cases Nos. 10266-HW and 10391-HW; which, together with copy of reporter's transcript of proceedings on March 22, 1950 in cases Nos. 10266 and 10391-HW; copy of reporter's transcript of proceedings on June 22, 23, 24, July 5, 6, 7, 8 and 13, 1949 in case number 20596-Criminal and original plaintiff's exhibits Nos. 1 to 25, inclusive, and original defendant's exhibits A to L, inclusive, and original Parkinson exhibit A in case No. 20596-Criminal, transmitted herewith, constitute the transcript of record on the appeals in cases numbered 10266 and 10391-HW to the United States Court of Appeals for the Ninth Circuit.

Witness my hand and the seal of said District Court this 25 day of August, A.D. 1950.

EDMUND L. SMITH,
Clerk.

[Seal] By /s/ THEODORE HOCKE,
Chief Deputy.

[Endorsed]: No. 12665. United States Court of Appeals for the Ninth Circuit. United States of America, Appellant, vs. El-O-Pathic Pharmacy, Martin A. Clemens, Hudson Products Company, Maywood Pharmacal Company and Allen H. Parkinson, Appellees. Transcript of Record. Appeal from the United States District Court for the Southern District of California, Central Division.

Filed: August 26, 1950.

/s/ PAUL P. O'BRIEN,
Clerk of the United States Court of Appeals for the Ninth Circuit.

United States Court of Appeals
for the Ninth Circuit

No. 12665

UNITED STATES OF AMERICA,
Appellant,

vs.

EL-O-PATHIC PHARMACY, a corporation, MARTIN A. CLEMENS, an individual, and VITA PHARMACALS, INC., a corporation,
Appellees.

UNITED STATES OF AMERICA,
Appellant,

vs.

HUDSON PRODUCTS COMPANY, a corporation, and its subsidiary firm doing business under the fictitious name and style, MAYWOOD PHARMACAL COMPANY, and ALLEN H. PARKINSON, an individual,
Appellees.

## STATEMENT OF POINTS ON WHICH APPELLANT INTENDS TO RELY ON THE APPEAL

Appellant hereby states the points upon which it intends to rely on appeal:

(1) The District Court erred in holding that the labeling of appellees' drugs bears adequate directions for use, within the meaning of 21 U.S.C.352 (f)(1).

(2) The District Court erred in holding that the labeling of appellees' drugs bears adequate warnings, within the meaning of 21 U.S.C. 352(f)(2), against use in those pathological conditions where their use may be dangerous to health.

(3) The District Court erred in holding that appellees' drugs are not dangerous to health, within the meaning of 21 U.S.C. 352(j), when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

(4) The District Court erred in holding that the labeling of appellees' drugs [the 5-milligram methyl testosterone linguets, and the combination methyl testosterone and Vitamin $B_1$ linguets] is not false or misleading within the meaning of 21 U.S.C. 352(a).

(5) The District Court erred in holding that appellant failed to establish that the daily intake of 5 milligrams of methyl testosterone in linguet form is ineffective in the treatment of male hormone deficiency.

(6) The District Court erred in holding that appellees' drugs are not misbranded within the meaning of 21 U.S.C. 352(a), (f)(1), (f)(2), and (j).

(7) The District Court erred in holding that appellant failed to sustain its burden of proof.

(8) The District Court erred in refusing to issue permanent injunctions as prayed to restrain the

appellees from further violations of the Federal Food, Drug, and Cosmetic Act.

Respectfully submitted,

ERNEST A. TOLIN,
United States Attorney,

CLYDE C. DOWNING,
Asst. U.S. Attorney,

/s/ GEORGE E. DANIELSON,
Asst. U.S. Atty.

Attorneys for United States of America, Appellant.

Affidavit of Service by Mail attached.

[Endorsed]: Filed August 30, 1950.